EXHIBIT GG

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

May 30, 1985

Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Dr. D. C. Marshall

cc: Ms. P. Britnell
Dr. A. W. Fetter
Mrs. B. F. Matlaga
Dr. J. R. McDivitt
Ms. J. Roy
ERFCF (85-219)

PROTOCOL FOR 10 YEAR IN VIVO STUDY
OF MONOFILAMENT SUTURES.

Your suggestions and concurrence with this protocol is sought. In vivo initiation date for the study is June 10, providing all of the samples have been delivered to ERF in timely fashion. Your input is needed for the protocol approval process to be completed on time.

Each of you is receiving their own copy of this "final" version of the protocol. It represents the combined input from ERF surgical, mechanical and morphological groups as well as the project leader, and groups outside ERF which will be analyzing chemical, optical and electronmicroscopic properties of explanted specimens by specific disciplinary and statistical techniques.

Please review the protocol, and annotate it with your comments and suggestions. Returning it to me as soon as possible will be appreciated.

N. R. Cholvin
Study Director

727F/8/wjm

PROTOCOL

PROLENE*, PVDF, ETHILON AND NOVAFIL SUTURE, MONOFILAMENT SIZE 5-0: BREAKING STRENGTH EVALUATION AFTER 2, 5, 7 AND 10 YEARS SUBCUTANEOUS IMPLANTATION IN THE BEAGLE DOG.

Sponsor	Testing Facility
ETHICON, Inc.	ETHICON Research Foundation
U. S. Route 22	ETHICON, Inc.
Somerville, NJ 08876	Somerville, NJ 08876

ERF Accession No. 85-219 Project No. 16102

Proposed date of initiation: June 3, 1985

Proposed date of completion (in vivo phase): June, 1995

Study Director _____ _____

N. R. Cholvin, D.V.M., Ph.D. Date

Section Manager, Experimental Surgery

Co-Investigator _____ _____

M. M. Heath, B.S. Date

Research Assistant

Co-Investigator_____ _____

E. Covington Date

Implantation Surgery Supervisor

Approved by_____ _____

A. W. Fetter, D.V.M., Ph.D. Date

Director, ETHICON Research Foundation

727F/wjm

PURPOSE

This study will be conducted to assess breaking strength and other parameters of PROLENE, PVDF, ETHILON and Novafil suture, monofilament size 5-0, after an *in vivo* residence of 10 years with interim periods of 2, 5, 7 years with baseline testing of unimplanted suture at each explant period.

TEST MATERIALS

PROLENE size 5/0 dyed, Lot #

ETHILON size 5/0 dyed, Lot #

Novafil size 5/0 dyed, Lot #

PVDF size 5/0 undyed Lot #

EXPERIMENTAL ANIMALS

Twenty-four healthy, mature, female Beagle dogs weighing approximately 7 to 10 kg (Marshall Beagles), will be used as the surgical models in this study. These dogs will be acclimated in the ETHICON Research Foundation (ERF) vivarium for a minimum of 2 weeks prior to use. Beagles are believed to be of adequate size and temperament for the purpose of this study and a large body of laboratory data is available on this breed for purposes of comparing any responses elicited.

Each dog will be identified by United States Department of Agriculture (USDA)

tattoos in the pinna of the ear. In addition, each dog will be assigned an ERF number.

The animals utilized in this study will be handled and maintained in accordance with the requirements of the Laboratory Animal Welfare Act (PL 89-544), its 1970 (PL 91-579) and 1976 (PL 94-279) amendments. Compliance for the above Public Laws will be accomplished by conforming to the standards promulgated in the Guide for the Care and Use of Laboratory Animals, DHEW Publication No. (NIH) 78-23, Revised 1978.

Dogs will be housed in the ERF facility for a minimum of 10 days postoperatively unless otherwise directed by the study director. Dogs then will be transferred to the Scott Research facility in Washington, NJ for the duration of the study.

Each dog housed at the Scott Research will be monitored daily by Scott Research personnel and monthly by ERF personnel for general condition and care. Should any animal require veterinary attention Scott Research will notify the study director.

Diet will consist of Purina Dog Chow (RALSTON PURINA), and tap water ad libitum except as indicated in surgical aftercare.

Further details for the housing and care of the dogs at Scott Research are enumerated in a contract dated March 1, 1984 and revised May 9, 1984.

METHODS

1. Anesthesia:

Each dog will be anesthetized with a 2.5% solution of SURITAL (PARKE-DAVIS) administered intravenously. This solution will be administered slowly until a sufficient level of anesthesia is obtained for endotracheal intubation. The endotracheal tube will then be attached to a VETAFLEX 5 (PITMAN-MOORE) Veterinary Anesthesia Machine. Anesthesia for the remainder of the the preparation and surgical procedures will be maintained by closed circuit inhalation of METOFANE (PITMAN-MOORE).

2. Surgical Preparation:

Depilation of the dorsum and lateral thorax will be accomplished with an electric animal clipper equipped with a surgical shaving blade. The area will be vacuumed to remove hair clippings and debris, then scrubbed with NOLVASAN (FORT DODGE), and water. Following scrubbing and drying, the entire area will be painted with tr. Merthiolate 1:1000 (ELI LILLY AND CO.).

3. Surgical Procedure:

Prior to implantation, all sutures will be 100% inspected by a staff member in the

Suture Technology Section using approximately 25X magnification to ensure that no surface damage exists as described for PROLENE in Ethicon's Finished Goods Specification #40, Issue 4, Appendix VII. Personnel conducting the examination will be trained to insure that proper aseptic technique is followed.

On each side of the thorax three small incisions, spaced approximately 5cm apart will be made through skin and cutaneous trunci muscle approximately 3.0cm from and perpendicular to the midline. Another similar set of incisions will be made approximately 6.0 inches ventral to the initial incisions. A precut flanged segment of a 30cc polypropylene syringe barrel will be positioned subcutaneously in both the dorsal and ventral incisions so as to provide a sterile dam to isolate the subcutaneous implant sites from the cut surface of the skin during implantation.

A bougie (stainless steel intramedullary 5/16" diameter bone pin) will be inserted into a cannula consisting of a 6 inch piece of commercial plastic drinking straw and the pair introduced into the dorsal skin dam. The bougie and cannula will then be carefully introduced into the subcutaneous tissue to exit through the ventral dam. The bougie will be carefully withdrawn and six, 6 inch strands of the appropriate sample will be manipulated through the cannula. The cannula will then be withdrawn and discarded, taking care that the strands remain straight in the implant bed. The suture ends will then be secured together both dorsally and ventrally with an LC-200 clip. Both ends of each suture bundle will be secured to the adjacent subcutaneous tissue with an LC-300 clip. The cutaneous trunci muscle then will be closed by size 4-0 PROLENE suture in a continuous pattern. The skin incisions will be closed with PROXIMATE skin staples. Similar procedures will be performed at the remaining two ipsilateral skin incision sites and three sites on

the opposite side of the dog. Five dogs per period will have sutures implanted in this fashion with an additional four dogs for replacement as indicated.

The implantation scheme is shown in Table 1.

4. Clinical Procedures

Blood samples will be obtained from all dogs for a complete blood count (CBC) which will include red cell count, white cell count, hemoglobin, hematocrit, differential and blood cell indices. Samples additionally will be drawn for a blood chemistry screen which will include A/G ratio, albumin, alkaline phosphatase, bilirubin, direct and total BUN/creatinine ratio, calcium, chloride, cholestorol, creatinine, gamma glutamyl transpeptidase, globulin, glucose, iron, LDH, magnesium, phosphate, potassium, SGOT, SGPT, sodium, total protein, triglycerides, urea nitrogen, and uric acid. Blood samples will be drawn for analysis before surgery and again approximately one week postoperative. Thereafter, samples will be taken on an annual basis in order to monitor the general health of the animals throughout the study. Analysis will be done by the Vet Lab Division of MetPath Inc., Hackensack, NJ 07603.

Pulse rate, body temperature, and respiration rate will be taken prior to surgery and daily postoperatively for 7 days following surgery as directed by the veterinary surgeon in charge. Dogs will be observed daily throughout the study to determine their health status on the basis of food consumption, excretion and general attitude.

Dogs will be vaccinated annually against canine distemper, hepatitis, leptospirosis, tracheobronchitis and parvovirus infections and every three years

for rabies as indicated by ERF personnel.

Body weight will be measured before surgery, and every three months thereafter until the scheduled explantation period.

5. Explantation

Five dogs at each period will be euthanatized by ERF personnel employing an intravenous injection of T-61 (NATIONAL LABORATORIES) euthanasia solution. Thoracic skin will be carefully reflected and the implants extracted from the subcutaneous tissues without physical stress. After explantation one strand of each sample immediately will be selected arbitrarily and placed with being allowed to dry in a capped, properly labeled test tube containing sterile deionized water. These will be submitted to the Analytical Chemistry Department for appropriate physical and chemical analytical testing. The other 5 strands of each sample will be examined by an ERF staff member for surface damage as described in Ethicon's Finished Goods Specifications #40, Issue 4, Appendix VII. These will then be placed in saline-soaked, prelabled towels, and delivered to Implantation Surgery for testing of mechanical products.

6. Suture Breaking Strength Procedure:

Five strands of each test article recovered from each site and those from the unimplanted baseline group will be evaluated on an Instron Universal Testing Instrument set in the tensiometric test mode utilizing the Instron Expanded Program. Suture breaking/tensile strength, modulus, elongation and other mechanical parameters will be recorded on a calibrated strip chart recorder and on disc file in the calibrated IBM computer.

All pulled segments will be forwarded to the Analytical Chemistry Department for additional testing.

The Instron parameters will be set as follows:

Instron - Model 1122

Load Cell - Tensiometric (Model No. AR2254-1, Serial No. 003)

Jaw Faces - Plastic

Jaw Pressure - 50 psi

Gauge Length - 1 inch

Chart Speed - 10 in/min (PVDF, ETHILON, NOVAFIL)

20 in/min (PROLENE)

Crosshead Distraction Rate - 5 in/min (PVDF, ETHILON, NOVAFIL, PROLENE)

7. Data Handling:

All recordings of mechanical test data, including peaks and numerical breaking strength values, will then be grouped and identified by the appropriate United States Department of Agriculture (USDA) tattoo and dog number.

At each test interval an interim report will be issued. Data will be recorded from each tested suture segment on the computer printout and stored on a floppy disc. It then will be proofread and run through the Program "Pounds" (ETHICON) to compute and/list % elongation, Young's Modulus, group average, confidence limits (95%), standard deviation, conversion to metric, percent remaining of implanted groups from baseline group, sample description and all Instron parameters. A final report will be written after testing the 10 year sample group.

Information obtained by staff in the Analytical Chemistry and Suture Technology sections will be reported separately.

ETHICON: "POUNDS" Program

ETHICON, Inc.

ETHICON Research Foundation

8. Data Storage:

Upon completion of this study, all relative raw and finished data, memorandums, and communications will be submitted to the ERF Central File.

TABLE I

RANDOMIZATION FOR 10-YEAR MONOFILAMENT SUTURE STUDY

Implantation Period (Yrs.)	Dog #	Suture Type For Each Site*					
		1	2	3	4	5	6
2	1	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
	2	PVDF	PROLENE	Novafil	ETHILON	PVDF	PROLENE
	3	ETHILON	Novafil	PROLENE	PVDF	ETHILON	PVDF
	4	Novafil	ETHILON	PVDF	PROLENE	PROLENE	ETHILON
	5	PROLENE	PVDF	Novafil	ETHILON	Novafil	PVDF
5	1	PROLENE	Novafil	ETHILON	PVDF	PROLENE	ETHILON
	2	Novafil	PROLENE	PVDF	ETHILON	Novafil	PROLENE
	3	ETHILON	PVDF	PROLENE	Novafil	PVDF	Novafil
	4	PVDF	ETHILON	Novafil	PROLENE	ETHILON	PVDF
	5	ETHILON	Novafil	ETHILON	PROLENE	PVDF	Novafil
7	1	ETHILON	PVDF	PROLENE	Novafil	Novafil	ETHILON
	2	PVDF	ETHILON	Novafil	PROLENE	PROLENE	Novafil
	3	PROLENE	Novafil	ETHILON	PVDF	PVDF	PROLENE
	4	Novafil	PROLENE	PVDF	ETHILON	ETHILON	PVDF
	5	Novafil	PROLENE	PROLENE	PVDF	ETHILON	ETHILON
10	1	Novafil	PVDF	ETHILON	PROLENE	PROLENE	Novafil
	2	PVDF	Novafil	PROLENE	ETHILON	PVDF	PROLENE
	3	ETHILON	PROLENE	Novafil	PVDF	ETHILON	PVDF
	4	PROLENE	ETHILON	PVDF	Novafil	Novafil	ETHILON
	5	PVDF	ETHILON	PVDF	Novafil	Novafil	PROLENE
Replacements**	1	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
	2	Novafil	ETHILON	PVDF	PROLENE	PVDF	PROLENE
	3	PVDF	Novafil	PROLENE	ETHILON	ETHILON	PVDF
	4	ETHILON	PROLENE	Novafil	PVDF	Novafil	ETHILON

* Site 1 = Left Cranial
Site 2 = Left Middle
Site 3 = Left Caudal
Site 4 = Right Cranial
Site 5 = Right Middle
Site 6 = Right Caudal

** Try to select a replacement dog with the same number of each suture type as the original.

07501/5

"B" SHEET: Experimental Surgery, Toxicology, and Cell Biology

ETHICON RESEARCH FOUNDATION

KILL SCHEDULE

ACCESSION NUMBER 85-219 DATE 6/18/85

MATERIAL(s) (test/control article) Prolene PVD7 Novafil Ethilon

NUMBER OF SAMPLES 4 EXPERIMENTAL ANIMAL (test system) Beagle

TOTAL NUMBER OF ANIMALS 24 NUMBER OF ANIMALS PER PERIOD 5 + 4 Replacement

EVALUATION BSS

ANIMAL NO.(s) (USDA NO.)*	TREATMENT DATE	OBSERVATION PERIOD	KILL DATE	COMMENTS
1993 (585921)	6/10/85	2yr	6/8/87	
1994 (583251)	6/11/85	5yr	week of 6/11/90	
1995 (600725)	6/11/85	7yr	week of 6/11/92	
1996 (589268	6/13/85	10yr	week of 6/13/95	
1997 (597333)	6/13/85	X	—	replacement
1999 (592285	6/17/85	2yr	6/15/87	
2000 (594865)	6/18/85	5yr	week of 6/18/90	

*WHEN APPLICABLE

EI 70-226

"B" SHEET: Experimental Surgery, Toxicology, and Cell Biology

ETHICON RESEARCH FOUNDATION

KILL SCHEDULE

ACCESSION NUMBER 85-219 DATE 6/18/85

MATERIAL(s) (test/control article) Prolene PVD7 Novafil Ethilon

NUMBER OF SAMPLES 4 EXPERIMENTAL ANIMAL (test system) Beagle

TOTAL NUMBER OF ANIMALS 24 NUMBER OF ANIMALS PER PERIOD 5 ± 4 replacement

EVALUATION BSE

ANIMAL NO.(s) (USDA NO.)*	TREATMENT DATE	OBSERVATION PERIOD	KILL DATE	COMMENTS
2001 (592161)	6/18/85	7yr	week of 6/18/92	
2002 (598453)	6/19/85	10yr	week of 6/19/95	✓
2003 (601080)	6/19/85	X	—	replacement
2005 (602868)	6/20/85	2yr	6/18/87	Died 2/15/86; Replaced ± #2009 KBG 12/9/86
2006 (598658	6/20/85	5yr	week of 6/20/90	
2007 (594091	6/24/85	7yr	week of 6/24/92	
2008 (591386)	6/25/85	10yr	week of 6/25/95	
2009 (59172)	6/25/85	X	—	KBG 12/9/86 replacement Replaces #2005

*WHEN APPLICABLE

EI 70-226

"B" SHEET: Experimental Surgery, Toxicology, and Cell Biology

ETHICON RESEARCH FOUNDATION

KILL SCHEDULE

ACCESSION NUMBER 85-219 DATE 6/26/85

MATERIAL(s) (test/control article) Poolene PVD7 Novafil Ethilon

NUMBER OF SAMPLES 4 EXPERIMENTAL ANIMAL (test system) Beagle

TOTAL NUMBER OF ANIMALS 24 NUMBER OF ANIMALS PER PERIOD 5 & 4 replacement

EVALUATION ~~BSE~~

ANIMAL NO.(s) (USDA NO.)*	TREATMENT DATE	OBSERVATION PERIOD	KILL DATE	COMMENTS
2011 (591505)	6/26/85	2yr	6/24/87	
2012 (597694)	6/27/85	5yr	week of 6/27/90	
2013 (594016)	6/27/85	7yr	week of 6/27/92	
2014 (601438)	7/1/85	10yr	week of 7/1/95	
2015 (590517)	7/1/85	x	—	replacement
2017 (602108)	7/9/85	2yr	7/7/87	
2018 (602329)	7/10/85	5yr	week of 7/10/90	

*WHEN APPLICABLE

EI 70-226

"B" SHEET: Experimental Surgery, Toxicology, and Cell Biology

ETHICON RESEARCH FOUNDATION

KILL SCHEDULE

ACCESSION NUMBER 85219 DATE 7/10/95

MATERIAL(s) (test/control article) Prolene, PVD7, Nurafil, Ethilon

NUMBER OF SAMPLES 4 EXPERIMENTAL ANIMAL (test system) Beagle

TOTAL NUMBER OF ANIMALS 24 NUMBER OF ANIMALS PER PERIOD 5 ≥ 4 replacem

EVALUATION BSE

ANIMAL NO.(s) (USDA NO.)*	TREATMENT DATE	OBSERVATION PERIOD	KILL DATE	COMMENTS
2019 (599719)	7/10/95	7yr	week 6 7/10/92	
2020 (588229)	7/10/95	10yr	week 6 7/10/95	

*WHEN APPLICABLE

EI 70-226

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

June 7, 1985

Ms. P. Britnell

PROLENE* PVDF, ETHILON AND NOVAFIL SUTURE, MONOFILAMENT SIZE 5-0: BREAKING STRENGTH EVALUATION AFTER 2, 5, 7 AND 10 YEARS SUBCUTANEOUS IMPLANTATION IN THE BEAGLE DOG. ERF ACC. NO. 85-219

cc: Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Dr. D. C. Marshall
Mrs. B. F. Matlaga
Dr. J. R. McDivitt
to
Dr. A. Melveger
Ms. J. Roy
to
Dr. T. S. Graves
RDCF

Attached is a copy of the above-referenced protocol.

Neal R. Cholvin

N. R. Cholvin, D.V.M., Ph.D.
Study Director

727F/wjm

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

June 7, 1985

PROTOCOL

PROLENE*, PVDF, ETHILON AND NOVAFIL SUTURE, MONOFILAMENT
SIZE 5-0: BREAKING STRENGTH EVALUATION AFTER 2, 5, 7 AND 10 YEARS
SUBCUTANEOUS IMPLANTATION IN THE BEAGLE DOG.

Sponsor	Testing Facility
ETHICON, Inc. U. S. Route 22 Somerville, NJ 08876	ETHICON Research Foundation ETHICON, Inc. Somerville, NJ 08876

ERF Accession No. 85-219 Project No. 16102

Proposed date of initiation: June 10, 1985

Proposed date of completion (in vivo phase): July, 1995

Study Director N. R. Cholvin 6/6/85
N. R. Cholvin, D.V.M., Ph.D. Date
Section Manager, Experimental Surgery

Co-Investigator M. M. Heath 6/6/85
M. M. Heath, B.S. Date
Research Assistant

Co-Investigator N. R. Cholvin for 6/6/85
E. Covington Date
Implantation Surgery Supervisor

Approved by A. W. Fetter 6/7/85
A. W. Fetter, D.V.M., Ph.D. Date
Director, ETHICON Research Foundation

727F/wjm

PURPOSE

This study will be conducted to assess breaking strength and other parameters of PROLENE, PVDF, ETHILON and Novafil suture, monofilament size 5-0, after an *in vivo* residence of 10 years with interim periods of 2, 5, 7 years with baseline testing of unimplanted suture at each explant period.

TEST MATERIALS

PROLENE size 5/0 dyed, Lot # TC 7275
ETHILON size 5/0 dyed, Lot # TA 5061
Novafil size 5/0 dyed, Lot # 27635
PVDF size 5/0 undyed Lot # 1633223

EXPERIMENTAL ANIMALS

Twenty-four healthy, mature, female Beagle dogs weighing approximately 7 to 10 kg (Marshall Beagles), will be used as the surgical models in this study. These dogs will be acclimated in the ETHICON Research Foundation (ERF) vivarium for a minimum of 2 weeks prior to use. Beagles are believed to be of adequate size and temperament for the purpose of this study and a large body of laboratory data is available on this breed for purposes of comparing any responses elicited.

Each dog will be identified by United States Department of Agriculture (USDA) tattoos in the pinna of the ear. In addition, each dog will be assigned an ERF number.

The animals utilized in this study will be handled and maintained in accordance with the requirements of the Laboratory Animal Welfare Act (PL 89-544), its 1970 (PL 91-579) and 1976 (PL 94-279) amendments. Compliance for the above Public Laws will be accomplished by conforming to the standards promulgated in the Guide for the Care and Use of Laboratory Animals, DHEW Publication No. (NIH) 78-23, Revised 1978.

Dogs will be housed in the ERF facility for a minimum of 10 days postoperatively unless otherwise directed by the study director. Dogs then will be transferred to the Scott Research facility in Washington, NJ for the duration of the study.

Each dog housed at the Scott Research will be monitored daily by Scott Research personnel and periodically by ERF personnel for general condition and care. Should any animal require veterinary attention Scott Research will notify the study director.

Diet will consist of Purina Dog Chow (RALSTON PURINA), and tap water *ad libitum* except as indicated in surgical aftercare.

Further details for the housing and care of the dogs at Scott Research are enumerated in a contract dated March 1, 1984 and revised May 9, 1984.

METHODS

1. Anesthesia:

Each dog will be anesthetized with a 2.5% solution of SURITAL (PARKE-DAVIS) administered intravenously. This solution will be administered slowly until a sufficient level of anesthesia is obtained for endotracheal intubation. The endotracheal tube will then be attached to a VETAFLEX 5 (PITMAN-MOORE) Veterinary Anesthesia Machine. Anesthesia for the remainder of the the preparation and surgical procedures will be maintained by closed circuit inhalation of METOFANE (PITMAN-MOORE).

2. Surgical Preparation:

Depilation of the dorsum and lateral thorax will be accomplished with an electric animal clipper equipped with a surgical shaving blade. The area will be vacuumed to remove hair clippings and debris, then scrubbed with NOLVASAN (FORT DODGE), and water. Following scrubbing and drying, the entire area will be painted with tr. Merthiolate 1:1000 (ELI LILLY AND CO.).

3. Preimplant Suture Inspection:

Prior to implantation, all sutures will be 100% inspected by a staff member in the Suture Technology Department using approximately 20X magnification to ensure that no surface damage exists as described in Ethicon's Finished Goods Specification #40, Issue 4, Appendix VII. Personnel conducting the examination will be trained to follow proper aseptic technique.

4. Surgical Procedure:

On each side of the thorax three small incisions, spaced approximately 5cm apart will be made through skin and cutaneous trunci muscle approximately 3.0cm from and perpendicular to the midline. Another similar set of incisions will be made approximately 6.0 inches ventral to the initial incisions. A precut flanged segment of a 30cc polypropylene syringe barrel will be positioned subcutaneously in both the dorsal and ventral incisions so as to provide a sterile dam to isolate the subcutaneous implant sites from the cut surface of the skin during implantation.

A bougie (stainless steel intramedullary 5/16" diameter bone pin) will be inserted into a cannula consisting of a 5 to 6 inch piece of 1/4" diameter thin walled disposable plastic tubing and the pair introduced into the dorsal skin dam. The bougie and cannula will then be carefully directed through the subcutaneous tissue to exit through the ventral dam. The bougie will be carefully withdrawn and six, 6 inch long strands of the appropriate sample, each bundle secured at both ends with an LC-200 clip, will be manipulated through the cannula. The cannula will then be withdrawn and discarded, taking care that the strands remain straight in the implant bed. Both ends of each suture bundle then will be secured to adjacent subcutaneous tissue with an LC-300 clip. The cutaneous trunci muscle then will be closed by size 4-0 PROLENE suture in a continuous pattern. The skin incisions will be closed with PROXIMATE skin staples. Similar procedures will be performed at the remaining two ipsilateral skin incision sites and three sites on the opposite side of the dog. Five dogs per period will have sutures implanted in this fashion with an additional four dogs for replacement if indicated.

The implantation scheme as developed by Statistics & Computer Applications Deaprtment, is shown in Table 1.

5. Clinical Procedures

Blood samples will be drawn for analysis before surgery and again approximately one week postoperative. Thereafter, samples will be taken on an annual basis in order to monitor the general health of the animals throughout the study. Analysis will be done by the Vet Lab Division of MetPath Inc., Hackensack, NJ 07603. Blood samples be obtained from all dogs will be subjected to a complete blood count (CBC) which will include red cell count, white cell count, hemoglobin, hematocrit, differential and blood cell indices. Samples additionally will be drawn for a blood chemistry screening test battery which will include A/G ratio, albumin, alkaline phosphatase, bilirubin, direct and total BUN/creatinine ratio, calcium, chloride, cholestorol, creatinine, gamma glutamyl transpeptidase, globulin, glucose, iron, LDH, magnesium, phosphate, potassium, SGOT, SGPT, sodium, total protein, triglycerides, urea nitrogen, and uric acid.

Pulse rate, body temperature, and respiration rate will be taken prior to surgery and daily postoperatively for 7 days following surgery as directed by the veterinary surgeon in charge. Dogs will be observed daily throughout the study to determine their health status on the basis of food consumption, excretion and general attitude.

Dogs will be vaccinated annually against canine distemper, hepatitis, leptospirosis, tracheobronchitis and parvovirus infections and every three years for rabies as indicated by ERF personnel.

Body weight will be measured before surgery, every three months thereafter and on the scheduled explantation date.

6. Explantation and Sample Inspections

Five dogs at each period will be euthanatized by ERF personnel employing an intravenous injection of T-61 (NATIONAL LABORATORIES) euthanasia solution. The thoracic skin will be carefully reflected and the implants extracted from the subcutaneous tissues without exposing them to physical stress. Immediately after explantation one strand of each sample will be randomly selected and without being allowed to dry placed in a capped, properly labeled test tube containing sterile deionized water. These samples will be submitted for analytical physical and chemical testing according to a protocol developed for this study by the Analytical Chemistry Department. The labeling will include dog number and site location. The other 5 strands of each sample will be examined by an ERF staff member for surface damage as described in Ethicon's Finished Goods Specifications #40, Issue 4, Appendix VII. These will then be placed in saline-soaked, prelabled towels, and delivered to Implantation Surgery for testing of mechanical properties.

7. Suture Breaking Strength Procedure:

Five strands of each test article recovered from each site will be evaluated on an Instron Universal Testing Instrument. Unimplanted samples, stored under existing room conditions, also will be tested at each time period. The testing instrument will be set in the tensiometric test mode utilizing the Instron/IBM "Expanded" program. Suture mechanical parameters will be recorded on the Instron calibrated strip chart recorder and on an IBM PC/XT computer disc file.

The Instron parameters will be set as follows:

Instron - Model 1122
Load Cell - Tensiometric (Model No. AR2254-1, Serial No. 003)
Jaw Faces - Plastic
Jaw Pressure - 50 psi
Gauge Length - 1 inch
Chart Speed - 10 in/min (PVDF, ETHILON, Novafil)
20 in/min (PROLENE)
Crosshead Distraction Rate - 5 in/min (PVDF, ETHILON, Novafil, PROLENE)

8. Data Handling:

All strip chart recordings of mechanical test data, including peaks and numerical breaking strength values, will then be grouped and identified by the appropriate United States Department of Agriculture (USDA) tattoo and dog number and filed.

All pulled segments will be forwarded to the Analytical Chemistry Department for additional testing. Each set of 5 strands will remain identified as to dog number and site location.

At each test interval an interim report will be issued. Data from each tested suture segment will be proofread and run through the Program "Pounds" (ETHICON) to compute and list breaking and tensile strengths, % elongation to break, Young's Modulus* and area under stress-strain curve. Also calculated will be breaking strength group averages, confidence limits (95%), standard deviation and percent strength remaining compared to the baseline group. A final report summarizing findings from all time periods will be written after testing the 10 year sample group.

Information obtained by staff in the Analytical Chemistry and Suture Technology Departments will be reported separately.

ETHICON: "POUNDS" Program
ETHICON, Inc.
ETHICON Research Foundation

*Young's Modulus calculations. Modulus values are functions of crosshead distraction rate and gauge length. The actual values obtained for these specimens will be inherently consistant within this study because the two sensitive test parameters will have been held constant. Direct comparisons with data obtained under different test conditions in other studies may not be valid.

9. Data Storage:

Upon completion of this study, all relvant raw and finished data, memorandums, and communications will be submitted to the ERF Central File.

Table I

RANDOMIZATION FOR 10-YEAR MONOFILAMENT SUTURE STUDY

Implantation Period (Yrs.)	Dog #	Suture Type For Each Site*					
		1	2	3	4	5	6
2	1	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
	2	PVDF	PROLENE	Novafil	ETHILON	PVDF	PROLENE
	3	ETHILON	Novafil	PROLENE	PVDF	ETHILON	PVDF
	4	Novafil	ETHILON	PVDF	PROLENE	PROLENE	ETHILON
	5	PROLENE	PVDF	Novafil	ETHILON	Novafil	PVDF
5	1	PROLENE	Novafil	ETHILON	PVDF	PROLENE	ETHILON
	2	Novafil	PROLENE	PVDF	ETHILON	Novafil	PROLENE
	3	ETHILON	PVDF	PROLENE	Novafil	PVDF	Novafil
	4	PVDF	ETHILON	Novafil	PROLENE	ETHILON	PVDF
	5	ETHILON	Novafil	ETHILON	PROLENE	PVDF	Novafil
7	1	ETHILON	PVDF	PROLENE	Novafil	Novafil	ETHILON
	2	PVDF	ETHILON	Novafil	PROLENE	PROLENE	Novafil
	3	PROLENE	Novafil	ETHILON	PVDF	PVDF	PROLENE
	4	Novafil	PROLENE	PVDF	ETHILON	ETHILON	PVDF
	5	Novafil	PROLENE	PROLENE	PVDF	ETHILON	ETHILON
10	1	Novafil	PVDF	ETHILON	PROLENE	PROLENE	Novafil
	2	PVDF	Novafil	PROLENE	ETHILON	PVDF	PROLENE
	3	ETHILON	PROLENE	Novafil	PVDF	ETHILON	PVDF
	4	PROLENE	ETHILON	PVDF	Novafil	Novafil	ETHILON
	5	PVDF	ETHILON	PVDF	Novafil	Novafil	PROLENE
Replacements**	1	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
	2	Novafil	ETHILON	PVDF	PROLENE	PVDF	PROLENE
	3	PVDF	Novafil	PROLENE	ETHILON	ETHILON	PVDF
	4	ETHILON	PROLENE	Novafil	PVDF	Novafil	ETHILON

* Site 1 = Left Cranial
Site 2 = Left Middle
Site 3 = Left Caudal
Site 4 = Right Cranial
Site 5 = Right Middle
Site 6 = Right Caudal

** Try to select a replacement dog with the same number of each suture type as the original.

07501/5

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

JAN 0 5 1989

Dr. S. Trenka-Benthin
Dr. G. Graves

cc: RDCF

SURGICAL BIOPSY REPORT

ERF ACCESSION NO.

85-219

PROJECT NO. 16102

Animal No.: 2013
Species: Canine
Submission Date: 12/14/88

Clinical Summary:

This dog was under a 10 year suture study and the implant was placed in July, 1985. A swollen right fifth mammary gland was noted in December, 1988. Both right fourth and fifth mammary glands were removed and ovariohistorectomy was performed.

Gross Description:

The fifth mammary gland was enlarged, 2.5 x 2.5 x 2 cm, and cystic on cut surface. The cysts contained pink tinged clear fluid. Both uterine horns were slightly enlarged with occasionally observed cystic foci. The ovaries were unremarkable.

Microscopic Description:

Mammary glands: The glands were multifocally dilated and contained lobules of neoplastic epithelial cells. The nuclei were fairly uniform in size and shape.

Uterus: The endometrium was hyperplastic. Dilated uterine glands were often seen. Occasionally, there were nests of endometrial glands embedded in the myometrium.

Ovaries: No significant lesion.

Final Diagnosis:

1. Mammary cystadenoma, right fifth mammary gland.
2. Mild adenomyosis with mild endometrial hyperplasia.

Comments

This is a benign mammary tumor and the surgical margin is good. Adenomyosis of the uterus is considered an incidental finding.

Sylvia H. Liu
Veterinary Pathologist

3013E/lat

ETHICON, INC.
a Johnson & Johnson company
SOMERVILLE NEW JERSEY · 08876-0151

August 21, 1987

Dr. D. Stoloff

cc: Mr. R. Lilenfeld
Dr. P. Moy
Dr. B. Schwartz
Dr. A. Skinner
Mr. K. Sullivan

10 YEAR BSR

This memo will serve as documentation regarding changes to the Instron test conditions for the subject study. These parameters were recommended by Dr. P. Moy, and previously communicated to both you and Mr. Sullivan verbally.

Chart Speed - 20 in./min. for all products
Crosshead Distraction Rate - 10 in./min. for all products

These changes were requested to standardize testing conditions for all materials. In addition, running at these conditions will permit direct comparison with historical data bases.

Please ensure that this change, along with previously documented changes (such as the decision to not utilize a specialized computer program, changes to areas doing test calculations, etc.) become a permanent revision to the protocol.

Thank you.

Nancy R. Myirski
Nancy R. Myirski

sac/0041c/81

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

July 3, 1986

ERF CF #85-219

cc: Ms. P. Britnell
Ms. E. Covington
to
Mr. R. Blocker
Dr. A. W. Fetter
ERF CF #85-226
RDCF

CLARIFICATION OF NUMBERS OF UNIMPLANTED STRANDS TO BE TESTED ON EXPLANT DATES:
PROLENE* POLYPROPYLENE SUTURE, PVDF, ETHILON* NYLON SUTURE AND NOVAFIL SUTURE, MONOFILAMENT SIZE 5-0 BREAKING STRENGTH EVALUATION - TEN YEAR STUDY

At each explant/test period in the aforementioned studies, a total of ten (10) unimplanted strands of each test sample will be tested for breaking strength according to the prescribed protocol. Each strand shall be obtained from a separate suture package. Sets of samples have been retained for this purpose.

N. R. Cholvin

*Trademark
s1/4005A/24

PROTOCOL REVISION

June 18, 1985

Acc. No: ERF 85-219

Study Director: N. R. Cholvin

Title of Study: PROLENE, PVDF, ETHILON and Novafil Suture; Monofilament size 5-0: Breaking Strength Evaluation after 2, 5, 7 and 10 years Subcutaneous Implantation in the Beagle Dog.

It has become necessary to change the following item(s) in the above described protocol:

1. Suture inspection, presurgical and at explantation, will be conducted under 10x magnification.

2. Suture strands will be clipped together employing LC 100 Ligaclips. Each bundle will then be attached to subcutaneous tissues by LC-300 Ligaclips.

3. Dog weights will range from 6 to 10kg preoperatively.

The reason(s) for the necessary change(s) are:

1. Suture imperfections can be adequately visualized at this power thus facilitating inspection ease and speed.

2. Suture strands were found to slip from the ligaclip during manipulation. The smaller clip held the strands more securely.

3. Due to the number of dogs in this study, the weight range was extended to include a larger pool from which to choose.

The change(s) will be initiated as of June 10, 1985

N. R. Cholvin 6/17/85

Study Director Date

THIS FORM MUST BE APPENDED TO THE PROTOCOL DESCRIBED HEREIN

727F/9/wjm

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF CF (ACCESSION NO. 85-219)

September 27, 1985
cc: Mr. G. Wallace
RDCF

HEARTWORM PROPHYLAXIS FOR DOGS
HOUSED OFF SITE.

Prophylactic treatment of housed dogs housed at Scott Research against Dirofilaria immitis infestation is deemed unnecessary unless periodic blood tests disclose microfilaria. The reason for this judgement is that the area in which ETHICON dogs are housed appears to be sufficiently insect-proofed.

N. R. Cholvin

N. R. Cholvin

3179A/wjm

ETHICON, INC.
a Johnson & Johnson company
P.O. BOX 151
SOMERVILLE • NEW JERSEY • 08876-0151

May 29, 1992

Mark Cofone
Susan Trenka-Benthin

cc: J. Lefelar
B. Matlaga
J. McVey
A. Melveger
RDCF

TEN YEAR IN VIVO STUDY: SCANNING ELECTRON AND LIGHT MICROSCOPY
INTERIM REPORT ON DOG #1995 AFTER 6 YEARS, 10.5 MONTH, SR# 33788

CONCLUSIONS

- The only explanted suture still undamaged after 6 years and 10.5 months in vivo is the 5-0 PVDF suture.
- The two ETHILON™ sutures from two different sites show the heaviest damage. Cracking starts in the top, black dyed layer; that layer is then lost due to abrasion and cracking will then occur in the undyed underlying layer of the suture. The abrasion is so dramatic that a decrease in suture diameter can be observed at low magnification.
- Approximately 50% of the PROLENE™ suture surface was cracked due to degradation. In some areas a lower degree of surface change was found, which had not been observed before. These marks could very well be the early beginnings of the usual cracks.
- Of the two Novafil sutures only one showed several areas of heavy cracking. These cracks are probably not introduced during preparation of the sample. This holds true, with even higher certainty, for all the other suture damages.
- When these results were compared with the 5 year explants no dramatic changes were found, only an intensification of damage was observed.

INTRODUCTION

In August 1990 a five year report was issued describing explantation results of a ten year dog study "TEN YEAR IN VIVO STUDY SCANNING ELECTRON MICROSCOPY FIVE YEAR REPORT", by Elke Lindemann. The appearance of explanted sutures (ETHILON, PVDF, PROLENE, Novafil) from five beagle dogs was described. The next explantation, after 7 years, is to start in June 1992. However, after 6 years and 10.5 months dog #1995 died prematurely. This interim report presents the results of the microscopical examination of the explanted sutures from dog #1995.

EXPERIMENTAL

Dog #1995 had been implanted in November, 1985 with the following 5-0 sutures:

Site 1	ETHILON	(dyed)
Site 2	PVDF	(undyed)
Site 3	PROLENE	(dyed)
Site 4	Novafil	(dyed)
Site 5	Novafil	(dyed)
Site 6	ETHILON	(dyed)

Pieces of the above sutures were received in the microscopy lab in water in May 1992.

A 100% inspection of all the suture pieces was performed in the Olympus Video Light Microscope (LM). They were kept wet in water and examined under polarized transmitted light. Usually sutures would be examined in oil, however to eliminate the possibility of drying out and cracking after explantation they were examined in the water from their storage vials. This procedure does produce some color artifacts. Also lensing effects of the curved suture, in some cases, allow unwanted visualization of the damage of the suture's underside. Photomicrographs were taken at 285x magnification of a typical area of each explant, which usually included a damaged area.

A fragment of each suture, which included the damage, was then air dried over night and mounted and gold coated under vacuum to provide an electron conductive surface. The sutures were then examined in the JEOL JSM 840 AII (SEM) at 500x magnification.

RESULTS

Figure 1 shows the ETHILON suture from site 1. In the top micrograph (LM) an area is shown were the upper half of the suture is abraded enough to lose the dyed black surface layer. In the lower half of the suture cracks are seen in the still intact, i.e., dyed surface layer. In the lower SEM micrograph a typical cracked, but not abraded, area is shown.

In Figure 2 the PVDF suture from site 2 is presented. The top micrograph (LM) and lower micrograph (SEM) show the mostly undamaged surface with just a few longitudinal striations.

In Figure 3 the PROLENE suture from site 3 is shown. The top micrograph (LM) shows a type of damage and lensing of this damage which is also seen in the left lower micrograph (SEM). In the right lower micrograph (SEM) the more common PROLENE cracking is found.

Figure 4 shows the Novafil suture from site 4. In the top (LM) micrograph a few voids are found in an otherwise normal looking suture. In the lower (SEM) micrograph a roughening of the suture's surface is observed.

In Figure 5 the Novafil suture from site 5 is shown. The top micrograph (LM) shows a normal looking suture surface with just a hint of some cracks. The lower (SEM) micrograph shows a badly cracked area. It is possible that the area examined by SEM is further along the suture, into the cracked area, while the LM view is from the beginning of the cracked area. It is also possible, but less likely, that the vacuum exposure and drying could have intensified *in vivo* cracking that was already present.

In Figure 6 the ETHILON suture from site 6 is shown. In the (LM) micrograph an area is captured where all of the outer, dyed surface was abraded; cracks are found in the underlying undyed body of the suture.

In Figure 7 the SEM micrographs of the ETHILON suture from site 6 are shown. The top micrograph at 200x shows an area where under visual examination the left side of the suture is black and the right side was abraded leaving the underlying white surface. In the lower left micrograph the border between the dyed and the abraded area is shown at 500x. An increase in roughness from left to right is found. In the right lower micrograph a heavily abraded, damaged colorless area is shown.

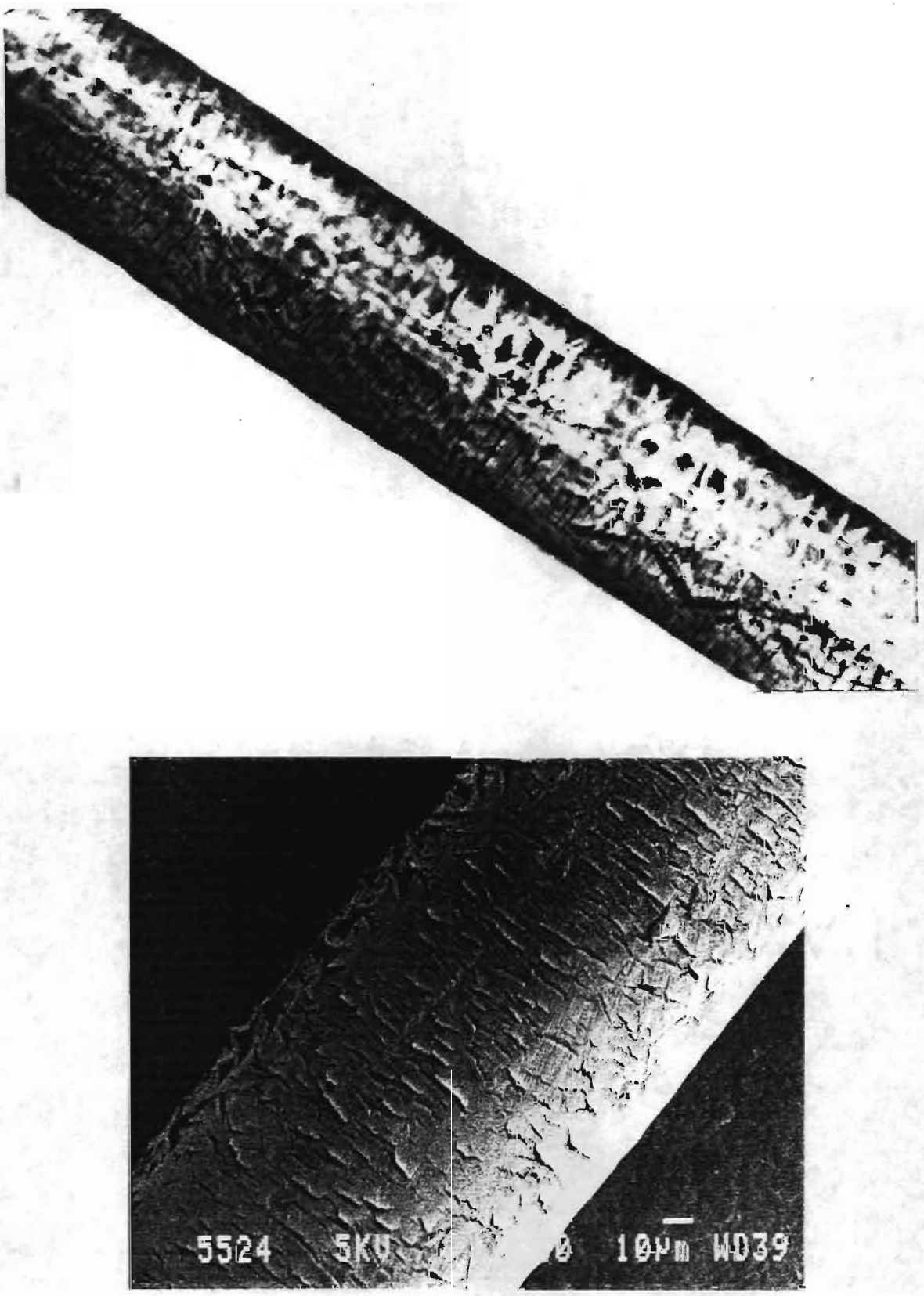
Elke Lindemann

Attachment

33788.EL

Figure 1

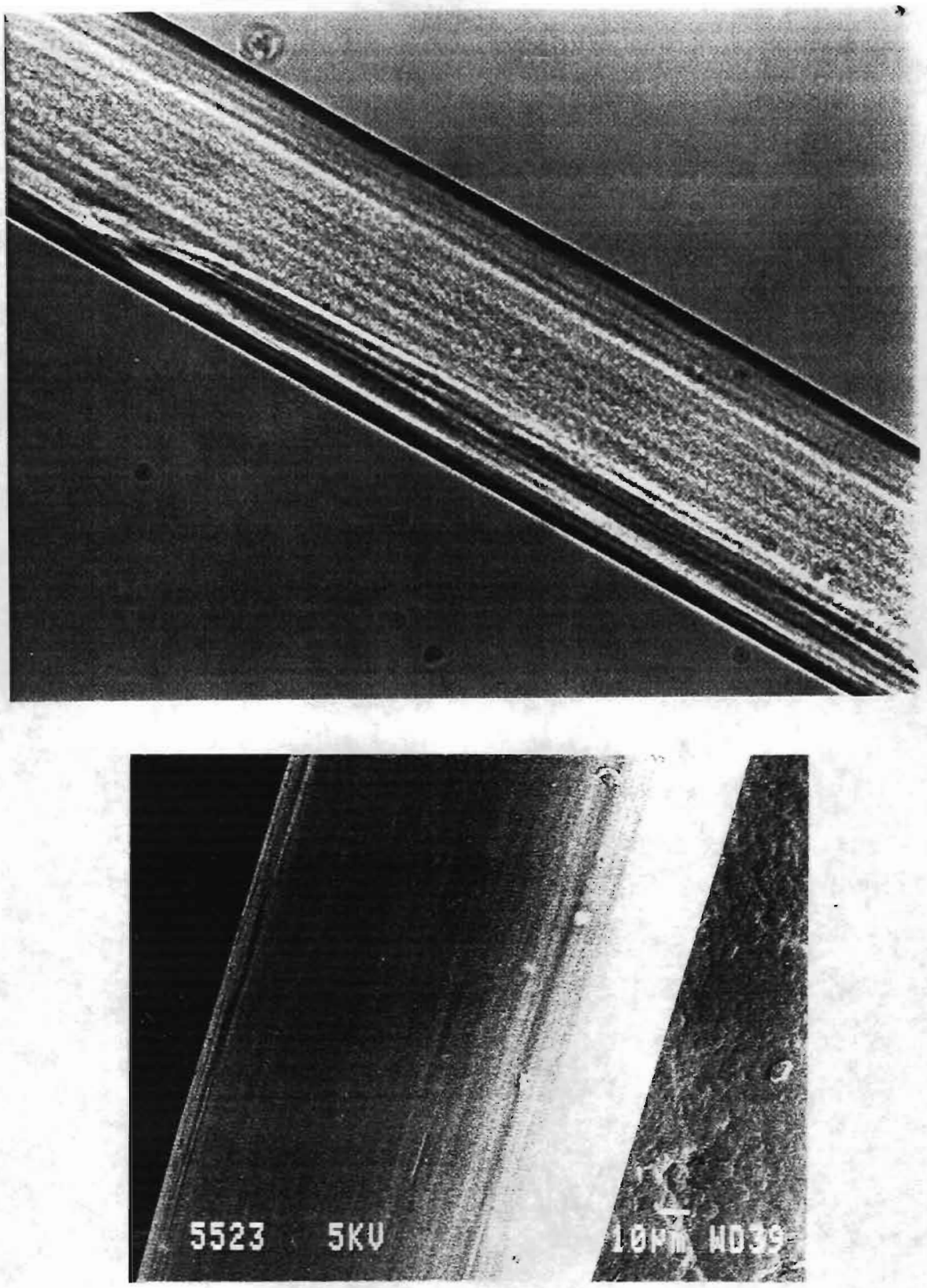
Ethilon Suture site 1



E. Lindemann SR# 33788 13/5/92

Figure 2

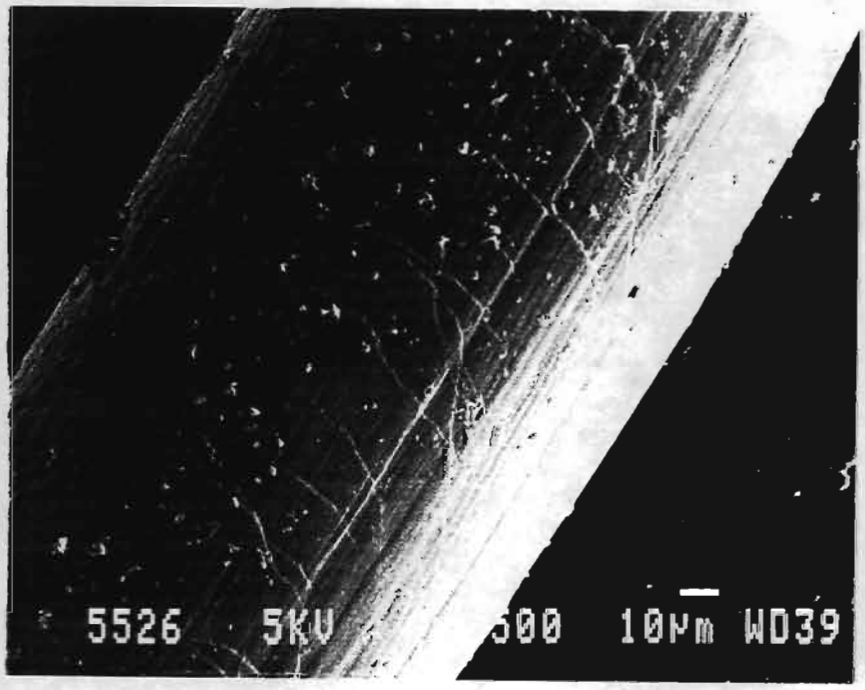
PVDF Suture site 2

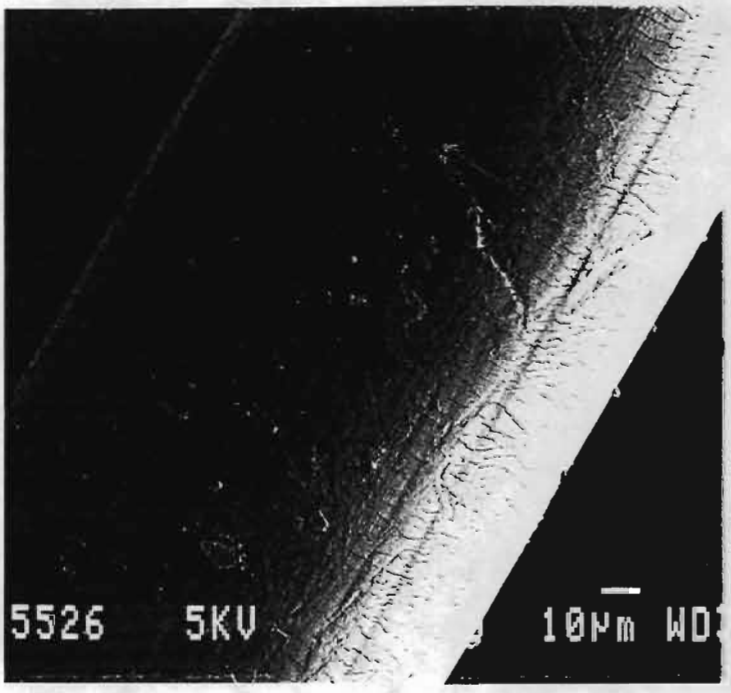


E. Lindemann SR# 33788 13/5/92

Figure 3

Prolene Suture site 3

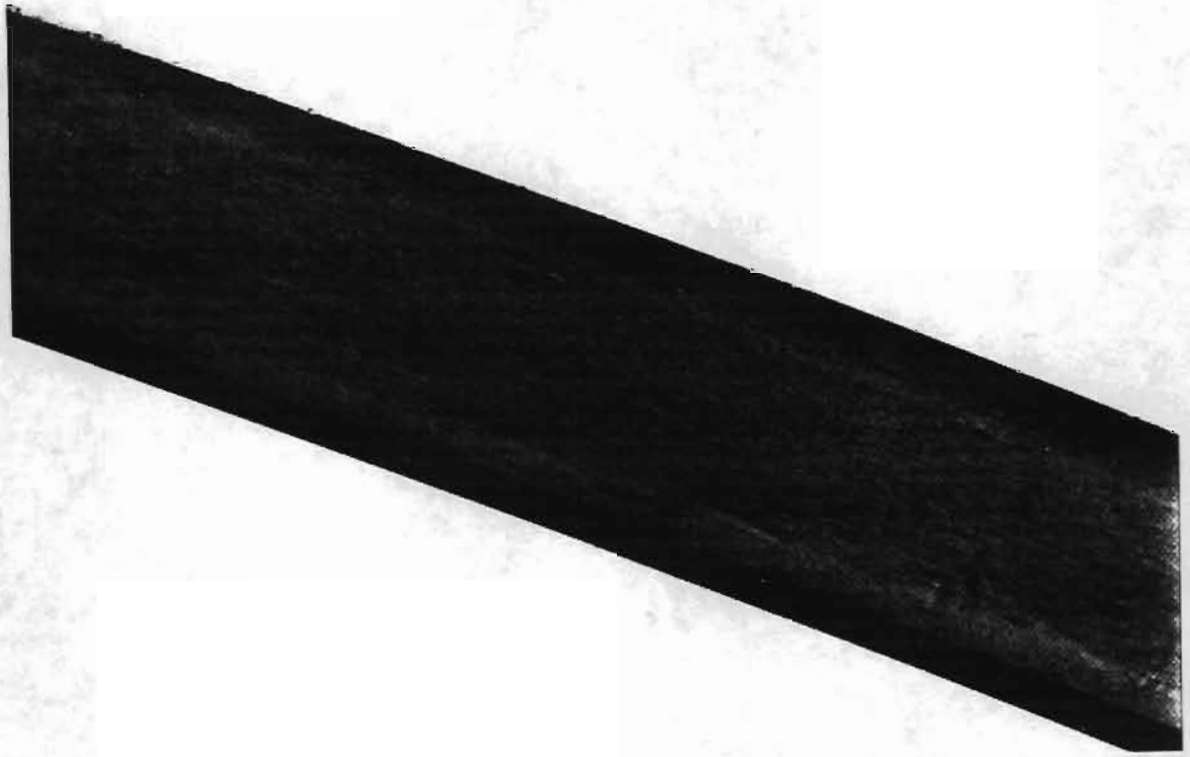


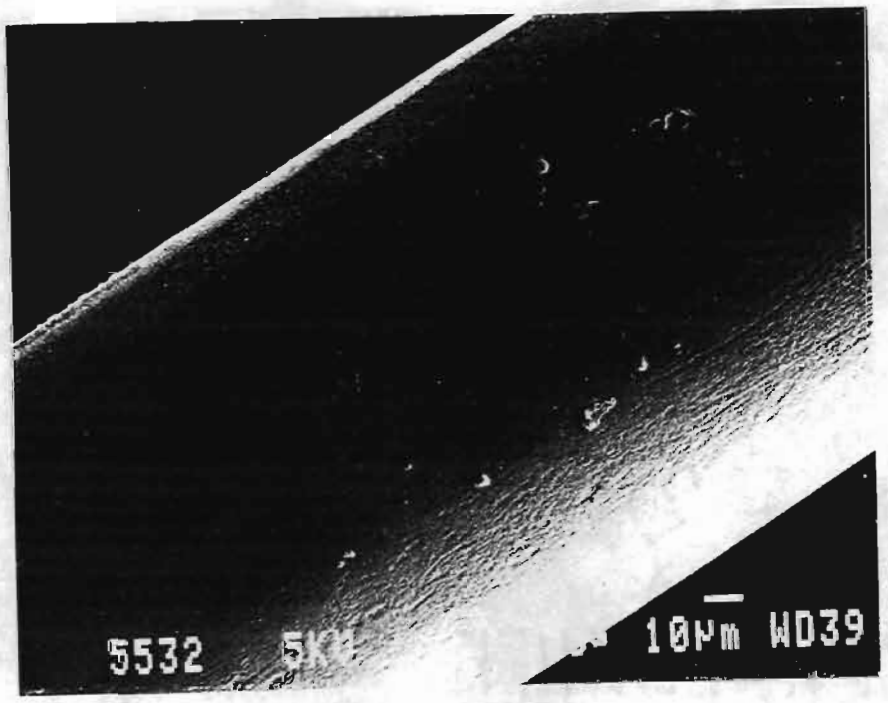


E. Lindemann SR# 33788 13/5/92

Figure 4

Novafil Suture site 4

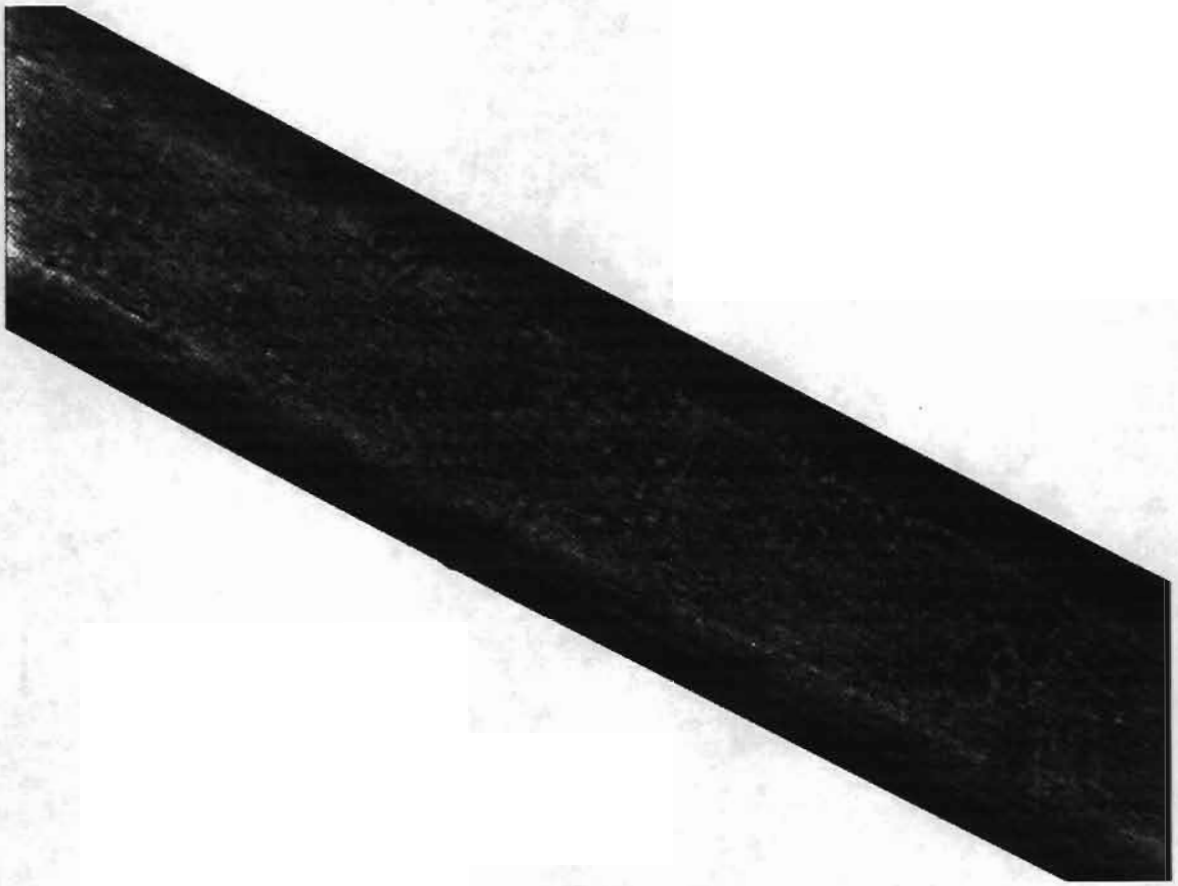


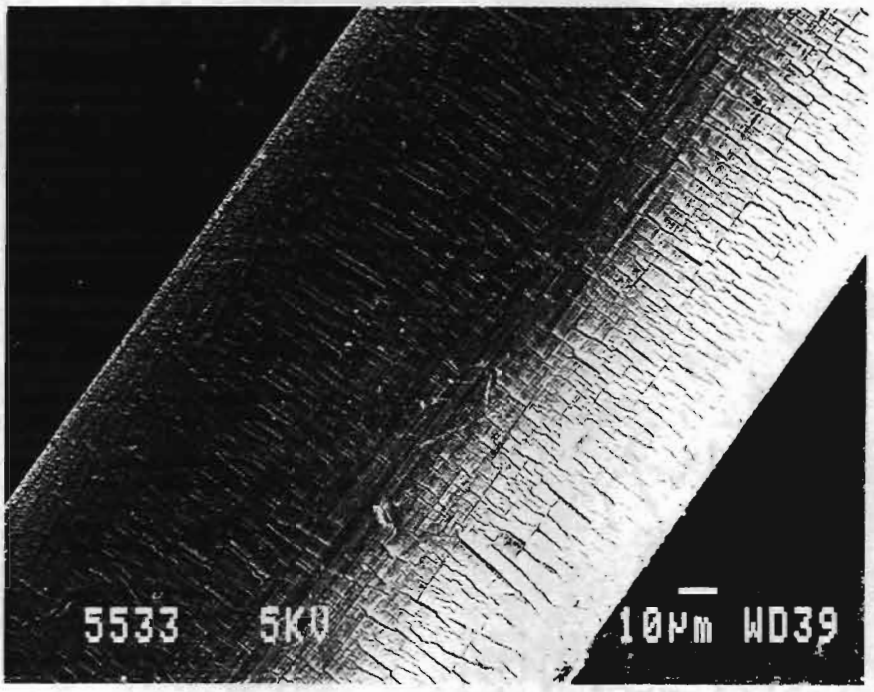


E. Lindemann SR# 33788 13/5/92

Figure 5

Novafil Suture site 5

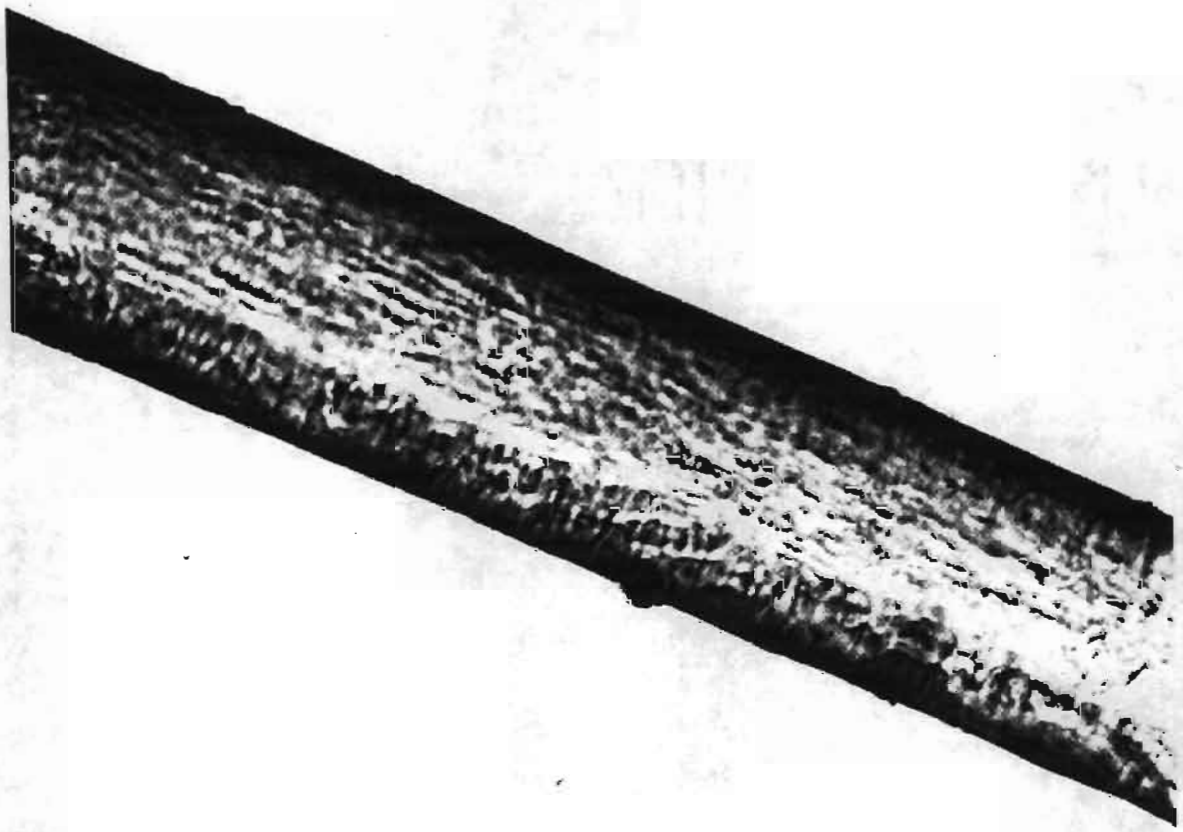




E. Lindemann SR# 33788 5/13/92

Figure 6

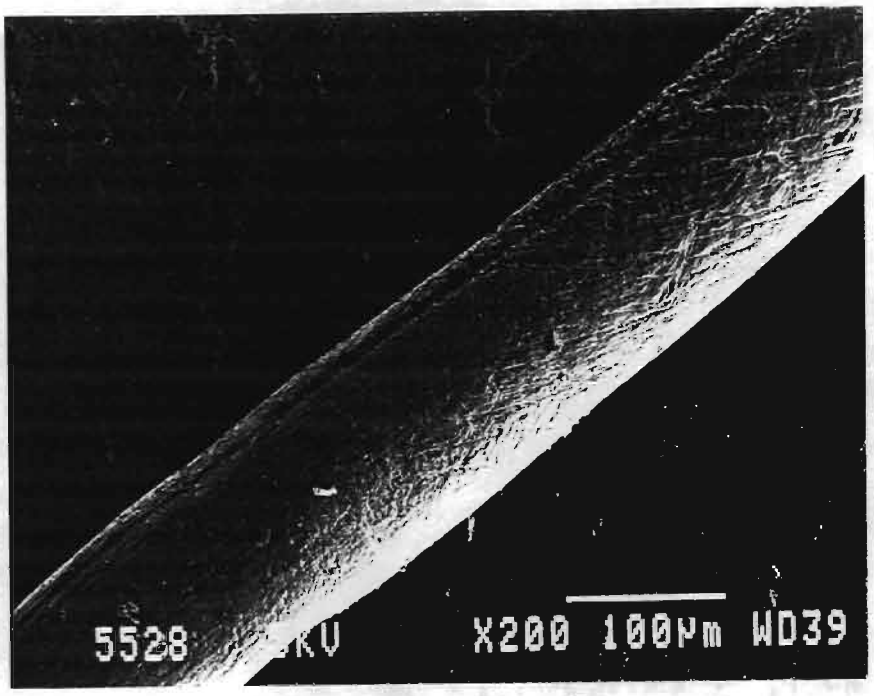
Ethilon Suture site 6



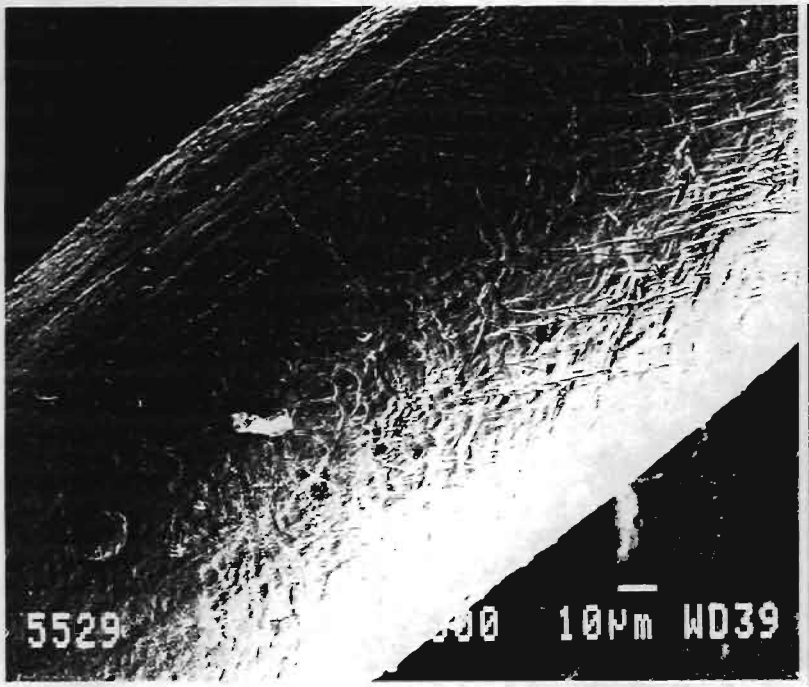
E. Lindemann SR# 33788 5/13/92

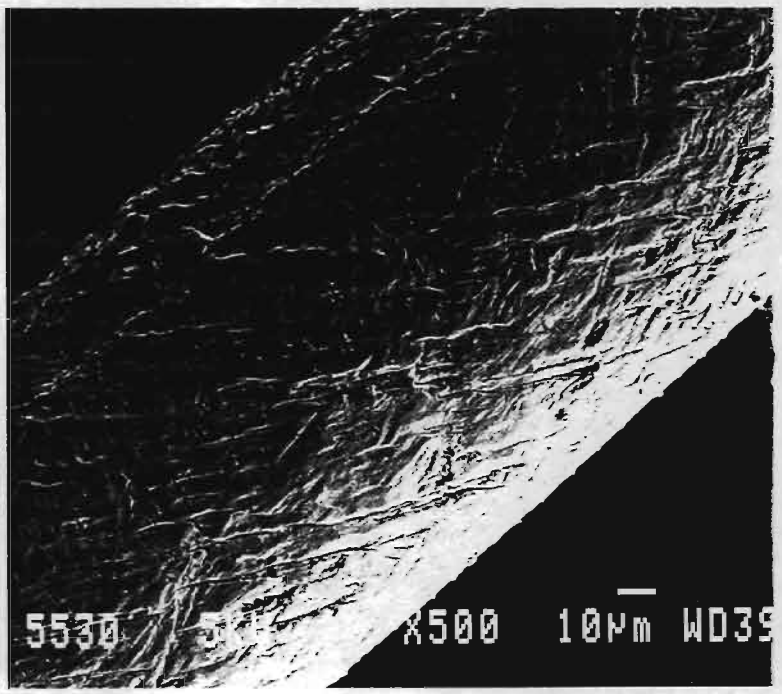
Figure 7

Ethilon Suture site 6



Black ⟷ Undyed





Black ⟷ Undyed

E. Lindemann SR# 33788 5/13/92

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE NEW JERSEY 08876

February 18, 1986

ERF Central File

cc: 85-219

INSPECTION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On January 22, 1986 M. M. Heath and N. R. Cholvin made a site visit to Scott Research, Washington, N.J.

Clinical examinations of the dogs on ERF # 85-219 were performed. The animals generally were in good physical condition. Few specific clinical problems were encountered. If a problem was detected, notation was made on the record.

All implant sites were quiescent. The implants were not palpable, indicating a paucity of tissue reaction.

The generalized dermatologic problem reported earlier in dog # 2017 had spontaneously regressed towards almost normal.

Several subcutaneous suture knots, used to close implant site skin incisions, had eroded up through the skin. These were removed and noted on the record for the affected animals.

Dog # 2008 exhibited a fibrotic interdigital mass which was thought to require surgical removal. About one week later it had regressed, however, so no treatment is planned unless there is recurrence.

Dog # 1995 exhibited an inflammation of the nictitating membrane of approximately one week duration. Treatment with an antibiotic ophthalmic ointment was inititated, although surgical treatment usually is indicated. This entity rarely regresses with local antibiotic treatment. Surgery was not deemed unnecessary, however, due to regression of the inflammation after several days of treatment with the ophthalmic ointment.

An ongoing phenomenon, predicated by housing two dogs to a run, is that the dogs quickly soil each other's haircoats with excrement when excited by feeding and cleaning operations, despite twice daily cleaning of runs. Consideration is underway to determine whether or not alteration of the daily schedule of feeding and pen cleaning will reduce soiling.

N. R. Cholvin

N. R. Cholvin

3737A/wjm

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

Dr. N. R. Cholvin

March 3, 1986

cc: Dr. A. W. Fetter
Mrs. M. Heath
Dr. W. D. Sheffield
Mr. G. Wallace
ERF CF

PROLENE TEN YEAR BSE STUDY:
ERF 85-219: MICROSCOPIC
FINDINGS IN DOG NO. 2005

Dog no. 2005 was euthanatized on 2/15/86 due to clinical manifestations of acute renal failure. There had been a history of recent exposure to ethylene glycol. The necropsy, performed off-site, revealed gross findings suggestive of acute tubular necrosis. Formalin-fixed specimens of both kidneys and stomach were transmitted to ERF by Mrs. Heath. The microscopic findings confirmed the historical, clinical and gross observations: acute tubular necrosis with many oxalate crystals within renal tubules.

S. Trenka-Benthin

S. Trenka-Benthin, D.V.M.

3790A/cal

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE NEW JERSEY 08876

Dr. N. R. Cholvin

May 15, 1986

cc: Dr. A. W. Fetter
Mrs. M. M. Heath
ERFCF 85-219

INSPECTION OF 10 YEAR STUDY
ANIMALS (ERF #85-219) AT
SCOTT RESEARCH

On April 21, 1986, Mrs. M. M. Heath and Dr. D. Stoloff made a site visit to Scott Research, RD 1, Washington, New Jersey.

Clinical examinations of all dogs on ERF Study Accession No. 85-219 were performed. All animals were generally in good physical condition.

Pulse rate, body temperature, respiratory rates and body weights of all dogs on study were within normal units. The following twelve animals had no clinical abnormalties: #s 1994, 1999, 2000, 2001, 2003, 2006, 2007, 2012, 2013, 2018, 2019 and 2020. The moist dermatitis of dog #2014 and the interdigital dermatitis of the left forepaw of dog #2008 previously observed were no longer present.

Improving skin lesions were apparent in dog nos. 1997 and 2017. Dermatologic lesions observed in four dogs (#s 2005, 2009, 2011 and 2015) were not present at the time of previous inspection (1/22/86). Truncal Alopecia had increased in dog #1993.

An excision of the prolapsed gland of the third eyelid (left) of animal #1995 was performed. A topical ophthalmic ointment was administered for a five day period followng surgery.

David Stoloff 5/16/86

D. Stoloff, D.V.M., M.S.

si/4005A/4

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF Central File

August 20, 1986

cc: Accession #85-219

DEATH OF ANIMAL ON STUDY
(ERF #85-219) AT SCOTT RESEARCH

On February 13, 1986, Mr. Andre Scott of Scott Research called to report that animal #2005, in the two year group, was ill. The illness was severe so we advised Mr. Scott to contact a local veterinarian and to institute immediate diagnostic and emergency supportive medical procedures. Dr. L. W. Wasser of Washington, New Jersey instituted these procedures.

Mr. Scott reported that the enclosure (run) housing this dog and its mate was adjacent to a repair site for a heating system pipe leak. The pipe, which contained a 1:1 mixture of water and ethylene glycol, had burst and had been repaired the previous day. Some of the fluid had spilled into these dogs' run. When the leak was spotted, the two dogs were moved to another run and not returned until the surfaces had been hosed down carefully and allowed to dry.

The affected dog showed symptoms similar to those described for ethylene glycol poisoning. Results of blood and urine specimens also tended to support this diagnosis.

The condition of animal #2005 continued to deteriorate so the decision was made to euthanatize it. The implants were removed by Mrs. M. M. Heath and returned to ERF for testing according to the study protocol.

Breaking strength data from the explanted specimens, as well as Mr. Andre Scott's report of the incident and the report of necropsy on #2005 by Dr. S. Trenka-Benthin, also are on file.

N. R. Cholvin

N. R. Cholvin
Study Director

si/4005A/5

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

December 16, 1986

ERF CF #85-219

cc: Dr. N. R. Cholvin
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff

INSPECTION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On December 10, 1986, Mrs. K. B. Braun and Dr. N. R. Cholvin made a site visit to Scott Research, Washington, N.J. Some had gained excess weight since the last examination. Mr. Scott will be given a copy of the examination record to use in adjusting feed consumption of the affected dogs.

Clinical examinations of all dogs on ERF #85-219 were performed. The animals were generally in good physical condition.

Pulse rates, body temperatures, respiration rates and body weights of all dogs on study were within normal limits. One protruding PROLENE suture was removed from an incision site in each of two dogs, #2018 and #2008. Two sutures were prominent under the skin in dog #2002 and were noted for future observation.

An ulcer was observed on the soft palate in dog #2008 and will be reexamined on the next site visit.

Dog #1996 was anesthetized with Surital for excision of a mass in the skin at site #2. The mass was firm and fibrous, overlying the cutaneous trunci muscle with no communication to the underlying implant site. Skin closure was accomplished with a continuous subcuticular line of 3-0 VICRYL so removal of skin staples/sutures is not required. Histology will be performed and recorded with the dog's records. Recovery from anesthesia was uneventful.

K B Braun
K. B. Braun, A.A.S.

Enclosure
4384A/kbb

ETHICON RESEARCH FOUNDATION
CLINICAL OBSERVATION
RECORD

Date ~~of Surgery~~ 12-10-86 USDA no. _____ Acc. no. 85-219

(lbs) Date of Death _____ Species/Sex _____ Project no. _____

WEIGHT CHANGE	Date	T	P	R	Clinical Observations	
—	1996	102.5	112	~~124~~	wt.=22 lbs. Anesthetized ☆ Sur/Hal. Round, nude, ulcerated	
#		(14cc Sur/Hal inj'd)			nodule @ midpt. of Site #2 inc, excised. No involvement	
					of suture strands. Mass was firm, overlying cutaneous	
					trunci muscle with no communication to the	
					underlying implant site. Submitted for histology.	NRC
+2	1999	101.8	124	28	wt = 34 lbs. Normal (implant sites, Eyes, tonsils, l.g.)	NRC
+1	1993	101.5	120	26	WT = 21 lbs Normal	NRC
+3	2000	103.2	140	36	wt = 25 lbs " "	NRC
+1	1994	102.5	120	26	WT = 24 " " "	NRC
+3	1995	102.5	88	24	WT = 28 " " "	NRC
-1	2001	102.7	108	24	WT = 21 " " "	NRC
+3	1997	102.6	112	32	WT = 26 " "	NRC
+1	2003	102.6	88	20	" = 23 " "	NRC
+4	2017	103.0	112	20	" = 25 " "	NRC
+2	2011	103.0	108	24	" = 19 " "	NRC
—	2002	102.2	140	40	" = 18 " " . 2 sutures @ Vent L1 + L2 are	
	~~2006~~				~~wt = 22 lbs~~ prominent under skin.	NRC
+3	2006	101.0	120	24	wt = 21 lbs "	NRC
+3	2012	103.2	112	28	" = 23 " "	NRC
+2	2018	103.4	80	24	" = 22 " " ↑suture removed RT-Vent	NRC
+1	2013	102.2	116	24	" = 20 " "	NRC
+1	2007	103.3	140	36	" = 18 " "	NRC
+2	2019	103.8	92	28	" = 20 " "	NRC
+5	2008	102.6	88	24	" = 24 " " 1 suture removed Rt dorsal #1	
CK NEXT TIME →					observed ulcer on soft palate ca 1 cm	NRC wound
+3	2014	101.4	88	20	" = 19 " normal	NRC
+2	2020	101.6	80	20	" = 18 " "	NRC
—	2015	102.8	100	24	" = 20 " "	NRC
+1	2009	103.2	140	35	" = 19 " "	NRC

NOA = No Observable Abnormalities

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

February 13, 1987

ERF Central File #85-219

cc: Dr. N. R. Cholvin
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace

INSPECTION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On January 30, 1987, Mrs. K. B. Braun made a site visit to Scott Research, Washington, New Jersey. Some dogs had gained excess weight since the last two examinations. Feed consumption of the affected dogs was reduced to control or prevent further weight gain.

Clinical examinations of all dogs on ERF #85-219 were performed. The animals were generally in good physical condition.

Pulse rates, body temperatures, respiration rates and body weights of all dogs on study were within normal limits. One suture was prominent under the skin in dog #2012 and was noted for future observation.

K B Braun
K. B. Braun, A.A.S.

Attachment
si/4005A/27

ETHICON RESEARCH FOUNDATION
CLINICAL OBSERVATION
RECORD

1-30-87

Date of Surgery _____ USDA no. _____ Acc. no. 85-219

Date of Death _____ Species/Sex _____ Project no. _____

	Date	T	P	R	Clinical Observations	
+1	2011	101.0	120	24	20 lbs sl. redness of skin	KBB
-	1993	101.5	144	32	21 lbs same	KBB
-1	2000	102.4	128	36	24 lbs pressure sore RF	KBB
	1994	102.4	104	28	24 lbs noa	KBB
-1	1995	102.5	92	28	27 lbs noa	KBB
+1	2001	102.4	128	28	22 lbs pressure sores LF+ RF	KBB
+1	2002	101.2	128	35	19 lbs noa	KBB
	1996	103.4	132	26	22 lbs sl. redness of extremeties & muzzle	KBB
+1	1997	102.0	120	32	27 lbs noa	KBB
	2003	102.2	116	24	23 lbs noa	KBB
-9	1999	103.2	128	32	25 lbs noa	KBB
	2017	102.6	108	28	25 lbs noa, cleaned ears	KBB
-1	2006	101.7	116	24	20 lbs noa	KBB
	2012	101.5	140	36	23 lbs Sm. red bump site 5 (poss. sut. knot below skin surface)	KBB
	2018	102.0	86	20	22 lbs noa	KBB
	2013	101.5	132	28	20 lbs noa - in heat	KBB
	2007	102.8	132	32	18 lbs noa - in heat	KBB
+1	2019	102.6	132	32	21 lbs noa	KBB
+1	2008	102.2	108	26	25 lbs noa	KBB
	2014	101.8	136	28	19 lbs noa	KBB
	2020	101.8	76	20	18 lbs noa - thick tartar buildup on molars	KBB
	2015	102.8	116	24	20 lbs noa - same as above	KBB
+1	2009	103.8	140	36	20 lbs noa - Tartar (as above)	KBB

NOA - No Observable Abnormalities

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

March 13, 1987

ERF Central File #85-219

cc: Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace

SITE VISIT OF 10 YEAR STUDY OF
ANIMALS AT SCOTT RESEARCH (ERF 85-219)

On February 5, 1987, Dr. Glenn Graves and Ms. Karen Braun made a site visit to the Scott Research facility in Washington, New Jersey. The 23 dogs of the study were generally found to be in good condition although some of the dogs appeared overweight. The facilities were clean and each dog had fresh water.

Pressure sores were noted on several of the animals (see Clinical Oberservation Record) over the anterior aspect of the carpus/metacarpus and the lateral aspect of the taisus. The pressure sores appeaed to be secondary to the animals laying on the concrete runs.

Severe tartar accumulation on the molars was noted in several dogs (see Clinical Observation Record). This tartar accumulation will necessitate anesthesia and dental cleaning in the future.

A small 2 mm skin lesion at site 5 was examined on dog #2012. The skin lesions apperaed to be a subcutaneous suture knot. No action at this time was taken and the site will be monitored in the future.

An 8 mm now displaceable umbilical hernis was noted n dog #2020. This hernis poses no acute danger at the present time.

Dog #2008 was inspectd and the soft palate ulcer previously noted (site visit 12/16/87) was healed.

G. M. Graves

Glenn M. Graves, D.V.M., M.S.

si/2279E

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE NEW JERSEY 08876

June 11, 1987

ERF CF #85-219

cc: Dr. W. D. Sheffield
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff

INSPECTION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On April 30, 1987, Mrs. K. Braun and Dr. G. Graves visited Scott Research in Washington, N.J. to examine the dogs which are housed there while on long term study. The housing and facilities were found to be clean and in satisfactory condition. Five of the twelve dog runs had the rectangular wooden resting pad, which is present in each run, covered with a soft vinyl. The wooden pads were covered to help alleviate the pressure sores and calluses which were noted during earlier inspections. The covered pads have been in place for 6 weeks. The remaining resting pads are to be covered by July, 1987.
Nineteen of 23 dogs exhibited significant weight loss as a result of dietary restrictions recommended by Drs. Cholvin and Graves since December 1986. Three dogs had remained at the same weight and 1 dog gained a pound. All dogs were near or at optimum weight and in good physical condition.

Clinical examinations showed that pulse rates, body temperatures and respiration rates of all dogs were within normal limits. All dogs had moderate to marked amounts of dental tartar present. Five dogs had areas of dermatitis with alopecia involving the dorsal and/or lateral thoracolumbar or lumbar regions.

Dog #1993 had a small (5 mm) firm mass of the right caudal mammary gland. Dog #1995 had a 1 cm firm mass in both right and left caudal mammary glands.

Dog #2018 had 2 interdigital growths (5 mm and 2 mm) between the 3rd and 4th digits on the right hind foot.

Dental scaling will be performed during the next scheduled visit (July, 1987) after the required plumbing fixtures have been installed to accomodate the Cavitron ultrasonic scaler.

K B Braun
K. B. Braun, A.A.S.

G. M. Graves
G. M. Graves, D.V.M., M.S.

4556A/kbb

ETHICON RESEARCH FOUNDATION
CLINICAL OBSERVATION
RECORD

4.30.87

Date of Surgery _____ USDA no. _____ Acc. no. 85-219

Date of Death _____ Species/Sex _____ Project no. _____

Date	T	P	R	Clinical Observations	
2011	102.0	92	24	1916. Alopecia bilat. dorsal lumbar + LF elbow ± sl. erythema	
		heavy		dental tartar	K66
1993	102.2	116	26	alopecia Rth-lum (dorsal); some tartar R caud-mam -5mm tumor	
		nails trimmed			
2000	103.3	108	26	dental tartar	
2008	102.1	108	24	dental tartar; areas of calous R+L lat malleoli	
2002	101.9	112	26	dental tartar	
1996	102.8	116	22	" "; alopecia R lat lumbar foci; calous bilat carpus &	
				metacarpus	
1995	102.1	68	20	dental tartar; 1cm firm mass R+L caud mam.	
2001	102.5	112	20	mod. dental tartar	
2003	102.0	108	22	dental tartar; mult. focal areas fibrosis R+L pinnas	
2017	103.2	104	24	tartar; focal area of alopecia ± open wond R caud lumbar	
1997	102.8	100	20	tartar;	
1994	104.0	132	28	tartar	
2006	102.0	124	24	tartar	
1999	103.5	128	26	tartar	
2012	102.8	112	20	tartar	
2018	102.8	68	20	tartar; RH pad #4 - worn, open wound, b/t d 3+4 - 2 interdigital	
				growths (2mm + 5-6mm dia.)	
2013	101.8	112	24	tartar	
2007	103.2	132	26	tartar	
2019	102.2	112	22	tartar	
2020	102.5	78	20	tartar; 3mm open sore lat. 2nd d. LR; 5mm non displ. umbilical hernia	
2014	101.8	104	24	tartar	
2009	103.8	124	28	tartar; thin haircoat over lat. thorac-lumbar regions —	
				pruritic; ant. dist. R legs - thickened skin, rough haircoat	
2015	103.8	108	20	tartar	

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

November 9, 1987

ERF Central File #85-219

cc: Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace
ERFCF #85-219

EXAMINATION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On July 23, 1987 Dr. G. Graves, Ms. D. Pursell and Mrs. C. Lawson, and on July 27, 1987 Dr. R. Ringwald, Mrs. K. Braun and Ms. D. Pursell conducted clinical examinations, vaccinations, and dental prophylaxis on the long-term study dogs housed at the Scott Research Facility, Washington, New Jersey.

Clinical examinations showed that body temperatures, heart and respiratory rates, and body weights were all within normal limits. Pressure sores were not evident on any of the animals. Fecal examinations, for internal gastrointestinal parasites, were negative. Fleas, and associated flea dermatitis, were found on several dogs. Treatment consisting of biweekly shampooing with a pyrethrin medicated shampoo will be instituted immediately.

Annual blood tests, which consisted of a CBC, Micro-Screen (serum chemistries, electrolytes, and liver enzymes), and Knott's Test, were performed on each dog. All blood test values were within normal parameters. All Knott's Tests were negative for microfilaria. Each dog received a dose of Quantum 6®, a polyvalent vaccine, which provides protection against canine distemper, adenovirus Type-2, parainfluenza, parvovirus, and leptospiral infections. Dental prophylaxis, which was conducted under general anesthesia, consisted of scaling and cleaning using the ultrasonic instrument.

In general, all dogs were found in good physical condition. The facilities were clean and each dog had fresh drinking water.

G. M. Graves, D.V.M., M.S.

R. Ringwald, D.V.M.

gmg/2642E

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF Central File #85-219

November 13, 1987

cc: Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace
RDCF

EXAMINATION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On October 28, 1987 Dr. G. Graves and Mrs. K. Braun conducted the quarterly clinical examinations on the 18 long-term study dogs housed at the Scott Research Facility, Washington, New Jersey.

Clinical examinations showed that body temperatures, heart and respiratory rates, and body weights were all within normal limits. Two dogs (#1996 and #2014) had a mild conjunctivitis of the left eye. A one week treatment with Trioptic® ophthalmic ointment was instituted. Fleas, with its associated flea dermatitis, and pressure sores were not detected on any of the dogs. The flea treatment, which was instituted in July, 1987 and consisted of biweekly shampooing with a pyrethrin medicated shampoo, was discontinued.

In general, all dogs were found in good physical condition. The facilities were clean and each dog had fresh drinking water.

G. M. Graves, D.V.M., M.S.

gmg/2642E

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF Central File #85-219

January 28, 1988
cc: Mrs. K. B. Braun
Dr. J. D. Paulson
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace
RDCF

EXAMINATION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On January 11, 1988 Dr. G. Graves and Mrs. K. Braun conducted the quarterly clinical examinations on the 18 long-term study dogs being housed at the Scott Research Facility, Washington, New Jersey.

Clinical examinations showed that body temperatures, heart and respiratory rates, and body weights of all dogs were within normal limits. Fleas, with its associated dermatitis, and pressure sores were not detected on any of the animals.

In general, all the dogs appeared to be in good physical condition. The facilities were clean and each dog had fresh drinking water.

G. M. Graves, D.V.M., M.S.

kbb/2710E

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF Central File #85-219

April 14, 1988

cc: Mrs. K. B. Braun
Dr. J. D. Paulson
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace
RDCF

EXAMINATION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On April 11, 1988 Dr. G. Graves and Mrs. K. Braun conducted the quarterly clinical examinations on the 18 long-term study dogs being housed at the Scott Research Facility in Washington, New Jersey.

Clinical examinations showed that body temperatures, heart and respiratory rates and body weights of all dogs were within normal limits. Blood was drawn and submitted to VetPath, Inc. for a Knott's Test (heartworm check) on all 18 dogs. All Knott's Tests were negative for microfilaria. For the prevention of heartworm disease, HEARTGARD 30® (ivermectin, 68 mcg, TM MERCK & CO.) tablets will be instituted immediately on a monthly basis and will be continued throughout the mosquito season. Fleas, with its associated dermatitis, and pressure sores were not detected on any of the animals.

In general, all the dogs appeared to be in good physical condition. The facilities were clean and each dog had fresh drinking water.

G. M. Graves, D.V.M., M.S.

2842E/kbb

ETHICON RESEARCH FOUNDATION
CLINICAL OBSERVATION
RECORD

Date ~~of Surgery~~ Examination: 4.11.88 USDA no. _____ Acc. no. 85-219

Date of Death _____ Species/Sex _____ Project no. 16102

Date	T	P	R	Clinical Observations		
2020	101.2	92	20	17 lbs sm area (L) vent/lat abd wall - alopecia + erythema.	Hwv	KBB
2007	101.1	120	28	15 lbs NOA	Hwv	KBB
2015	101.4	112	24	17 lbs. NOA	Hwv	KBB
2006	101.9	120	24	17 lbs NOA	Hwv	KBB
2018	102.0	84	20	17 lbs trimmed dewclaws; cut tail cut (R) vent - Knot under skin Crau.	Hwv	KBB
1997	101.5	112	24	20 lbs. Gen. focal erythema abd. w/ dermatitis	Hwv	KBB
2002	101.5	120	28	14# NOA trimmed nails	Hwv	KBB
1994	102.4	120	24	19# NOA trimmed nails	Hwv	KBB
2001	102.3	128	32	16# NOA	Hwv	KBB
1996	102.8	120	24	16# weaning of pads c some hemor.	Hwv	KBB
2012	101.5	120	28	15# abraided LH foot pad	Hwv	KBB
2019	101.8	116	24	15# NOA	Hwv	KBB
2000	102.7	112	28	15# NOA	Hwv	KBB
2003	102.4	100	24	19# NOA	Hwv	KBB
1995	102.6	92	20	16# NOA	Hwv	KBB
2013	102.7	116	28	18# trimmed nails	Hwv	KBB
2014	102.7	100	24	15# NOA	Hwv	KBB
2008	102.6	92	20	15# NOA	Hwv	KBB

NOA = No Observable Abnormalities

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

July 12, 1988

Mr. D. R. Brazel
to
Ms. E. Covington
Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Dr. J. R. McDivitt
to
Dr. A. Melveger
Dr. J. D. Paulson
Ms. J. Roy
to
Mr. M. J. McGrane
Dr. D. R. Stoloff

cc: RDCF

REVISION OF ERF PROTOCOL 85-219:
PROLENE* POLYPROPYLENE, PVDF, ETHILON* NYLON AND
NOVIFIL SUTURE, MONOFILAMENT SIZE 5-0,
BREAKING STRENGTH EVALUATION AFTER 2, 5, 7 AND 10 YEARS
SUBCUTANEOUS IMPLANTATION IN THE BEAGLE DOG

All study dogs will be transferred from the Scott Research Facility, Washington, New Jersey to the ETHICON Research Foundation for postoperative housing and care. The transfer of the 18 dogs currently on study will be completed by July 15, 1988.

Glenn M. Graves, D.V.M., M.S.
Study Director

1029F/lak

Attachment: Protocol Revision

* Trademark

PROTOCOL REVISION

Acc. No: ERF 85-219

Study Director: Dr. Glenn M. Graves

Title of Study: PROLENE* polypropylene, PVDF, ETHILON* nylon and Novafil suture, monofilament size 5-0, Breaking Strength Evaluation after 2, 5, 7 and 10 years: subcutaneous implantation in the Beagle dog.

It has become necessary to change the following item(s) in the above described protocol:

The study dogs currently housed at the Scott Research Facility, Washington, New Jersey will be transferred to the Ethicon Research Foundation for postoperative housing and care.

The reason(s) for the necessary change(s) is (are):

Facility improvements must be made at Scott Research.

The change(s) will be initiated as of July 12, 1988

G. M. Graves
Study Director

7/12/88
Date

THIS FORM MUST BE APPENDED TO THE PROTOCOL DESCRIBED HEREIN.

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

ERF Central File #85-219

DEC 21 1988

cc: Mrs. K. Braun
Dr. J. D. Paulson
Mr. A. Scott (Scott Research)
Dr. D. R. Stoloff
Mr. G. H. Wallace
RDCF

EXAMINATION OF 10 YEAR STUDY ANIMALS
(ERF #85-219) AT SCOTT RESEARCH

On July 6, 1988, Dr. G. Graves, Mrs. K. Braun and Ms. D. Pursell conducted clinical examinations and vaccinations on the 18 long-term study dogs housed at the Scott Research Facility in Washington, New Jersey.

Clinical examinations showed that body temperatures, heart and respiratory rates, and body weights were all within normal limits. Pressure sores were not evident on any of the animals.

Annual blood tests, consisting of a CBD and Micro-Screen (serum chemistries, electrolytes, and liver enzymes), were performed on each dog. All blood test values were within normal parameters. Each dog received a dose of Quantum 6* (a polyvalent vaccine which provides protection against canine distemper, adenovirus Type 2, parainfluenza, parvovirus and leptospiral infections).

In general all dogs were found in good physical condition. The facilities were clean and each dog had fresh drinking water.

G. M. Graves, D.V.M., M.S.

* Trademark

4578A/kbb

ETHICON RESEARCH FOUNDATION
CLINICAL OBSERVATION
RECORD

Exams
Date of ~~Surgery~~ 7.6.88

vaccine: G6
USDA no. K018-B048B 18MAY90 25APR91

Acc. no. 85-219

Date of Death

Species/Sex

Project no. 16102

	Date	T	P	R	Clinical Observations
+1	2014	101.8	132	24	wt-16 NOA
	2013	102.0	104	16	wt-18 NOA
+2	2008	102.6	80	12	17# tartar, buildup, alopecia over lateral and medial malleoli
+2	2000	102.8	104	16	17# ~~alopecia over (R) lat thorax/abdomen, alopecia over lateral and medial malleoli~~
	2003	103.0	100	24	19# lrn umbilical hernia
	2019	102.4	128	20	17# tartar buildup
+2	2012	103.4	140	34	17# NOA
	1996	103.2	124	20	16# Alopecia over carpal lat surfaces bilateral
	2001	103.4	142	32	16# NOA
+1	1994	103.2	120	30	20# NOA
+1	1997	102.6	96	20	21# NOA
	2002	103.6	120	24	14# Gen'l alopecia and rough, dull haircoat
	2006	103	120	panting	17# NOA
+1	2007	103.6	140	24	16# NOA
+1.5	2015	103.6	140	20	18.5# (L) otitis externa
+2	1995	103.4	124	16	18# (L) conjunctivitis & corneal ulcer - Rx-triple antibiotic oint TID x 7days
-1	2020	103.5	88	16	16# Umbilical hernia
	2018	102.8	64	20	17# Trimmed 3cm length of Proline tacking suture from (R) cranial lateral thoracic position

NOA = No Observable Abnormalities

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

JUN 15 1989

ERF Central File

cc: Mrs. K. Braun
Dr. D. R. Stoloff
Mr. G. Wallace
RDCF

EXAMINATION OF 85-219: 10 YEAR STUDY DOGS

On April 28 and 29, 1989 Dr. L. Senter and Mrs. K. Braun conducted clinical examinations of the 18 long-term study dogs.

Examinations showed that body temperatures, heart and respiratory rates and body weights were all within normal limits. Fifteen of the dogs were placed on a reducing diet due to a slight weight gain. All of the dogs had a high incidence of dental calculi. Teeth cleaning is scheduled for July.

In general, all the dogs appeared to be in good physical condition.

L. Senter, D.V.M., M.S.

4578A/kbb

PROTOCOL REVISION

June 18, 1985

Acc. No: ERF 85-219

Study Director: N. R. Cholvin

Title of Study: PROLENE, PVDF, ETHILON and Novafil Suture; Monofilament size 5-0: Breaking Strength Evaluation after 2, 5, 7 and 10 years Subcutaneous Implantation in the Beagle Dog.

It has become necessary to change the following item(s) in the above described protocol:

1. Suture inspection, presurgical and at explantation, will be conducted under 10x magnification.

2. Suture strands will be clipped together employing LC 100 Ligaclips. Each bundle will then be attached to subcutaneous tissues by LC-300 Ligaclips.

3. Dog weights will range from 6 to 10kg preoperatively.

The reason(s) for the necessary change(s) are:

1. Suture imperfections can be adequately visualized at this power thus facilitating inspection ease and speed.

2. Suture strands were found to slip from the ligaclip during manipulation. The smaller clip held the strands more securely.

3. Due to the number of dogs in this study, the weight range was extended to include a larger pool from which to choose.

The change(s) will be initiated as of June 10, 1985

N. R. Cholvin 6/17/85

Study Director Date

THIS FORM MUST BE APPENDED TO THE PROTOCOL DESCRIBED HEREIN

727F/9/wjm

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

TO: Geo. Wallace

cc: ERF CF

SUBJECT: RECORD OF ANIMAL EUTHANATIZED

Date of Surgery 6-25-85

Project # 16102

ERF Exper. # 85-219

ERF Animal # 2009

USDA # 591726

Date of Death 6-23-87

P.I. Period 2yr.

Sex female

Species canine

K Braun
Signature

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

TO: G. Wallace

cc: ERFCF

SUBJECT: RECORD OF ANIMAL EUTHANATIZED

Date of Surgery 6-17-85

Project # 16102

ERF Exper. # 85-219

ERF Animal # 1999

USDA # 592285

Date of Death 6-15-87

P.I. Period 2 yr.

Sex female

Species canine

K Braun
Signature

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

TO: J. Wallace

cc: ERF CF

SUBJECT: RECORD OF ANIMAL EUTHANATIZED

Date of Surgery 6-10-85

Project # 16102

ERF Exper. # 85-219

ERF Animal # 1993

USDA # 585921

Date of Death 6-8-87

P.I. Period 2 yr.

Sex Female

Species Canine

K Braun
Signature

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

TO: Geo. Wallace

cc: ERF CF

SUBJECT: RECORD OF ANIMAL EUTHANATIZED

Date of Surgery 6-26-85

Project # 16102

ERF Exper. # 85-219

ERF Animal # 2011

USDA # 591505

Date of Death 6-24-87

P.I. Period 2 yr.

Sex female

Species canine

K Braun
Signature

ETHICON
RESEARCH
FOUNDATION

SOMERVILLE, NEW JERSEY 08876

TO: Geo. Wallace

cc: ERF CF

SUBJECT: RECORD OF ANIMAL EUTHANATIZED

Date of Surgery 7-9-85

Project # 16102

ERF Exper. # 85-219

ERF Animal # 2017

USDA # 602108

Date of Death 7-8-87

P.I. Period 2 yr.

Sex female

Species canine

K. Braun
Signature

ETHICON RESEARCH FOUNDATION: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 1993 SPECIES Canine SEX Fe BODY WT. 7.5 kgms

DATE 6-8-87 DAYS P.I. 2 yr. KILLED T-61 DIED ___ REFERENCES 10 YR. BSR Study

All suture bundles visible and easily removed from subcutaneous fascia.

LC100's were intact at both ends of all bundles.

Fascia was slightly difficult to strip off suture bundles without stressing or traumatizing sutures - every effort was made to avoid this. Sutures were kept wet with Saline or sterile water and moistened gauze sponges were used to gently "pull" fascia from sutures.

One suture strand from each bundle (6 in total) was placed in a plain (no additive, red-top) 15ml tube filled with sterile water and submitted, with an Analytical Chemistry Service Request form, to Frank Schiller for SEM evaluation.

The remaining 5 strands were placed in Saline-wetted paper towels labeled with the acc. no., dog no. and site no. and inspected under magnification by Ann Archibold. Following inspection, the sutures were tested on the Instron by Kevin Sullivan. Suture fragments were sent to Gene Muse & Dan Burkley for IR and molecular weight determinations.

acc# 85-219

PHOTO ___ EXAMINER K Braun DATE 6-8-87

WITNESS Kevin Sullivan DATE 6-8-87

ETHICON RESEARCH FOUNDATION: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 1999 SPECIES canine SEX F BODY WT. 10.5 kgms

DATE 6-15-87 DAYS P.I. 2 yrs. KILLED T-61 DIED ____ REFERENCES 10 YR. PVDF/PROLENE BSR study

(Same as Dog # 1993)

all sutures visible and easily removed from subcutaneous fascia.

LC100's were intact at both ends of all bundles except @ site #6, dorsal end = 2 suture strands had slipped out, but were not displaced very far.

To remove suture bundles, either the dorsal or ventral LC100 was dissected free from fascia and the sutures cut at the clip. The opposite LC100 was then dissected from fascia and the whole bundle was gently pulled through the tissue tunnel until completely extracted from tissue. The remaining LC100 was removed by cutting the sutures at the clip. The sutures were immediately immersed in saline when removed from the tissue.

1 suture strand from each bundle was placed in a test tube containing sterile water and submitted to Frank Schiller, for SEM.

The 5 remaining strands were placed in saline-soaked paper towels and inspected by Ann Leibold under magnification. Following inspection, the sutures were tested on the Instron by Kevin Sullivan. Suture fragments were submitted to Gene Muse/Dan Burkley for IR and molecular weight determinations.

PHOTO ____ EXAMINER K. Braun DATE 6-15-87

WITNESS ____ DATE ____

ETHICON RESEARCH FOUNDATION: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 2009 SPECIES canine SEX F BODY WT. 8.4 Kgms

DATE 6-23-87 DAYS P.I. 2 yr. KILLED T-61 DIED ___ REFERENCES 10 YR. BSE Study

Same as dog # 1999 6/15/87

All sutures were visible and easily removed from SQ fascia.

LC100's were dissected from the fascia. The dorsal LC100 was cut off the sutures and the suture bundle was extracted from the fascia by pulling on the ventral LC100. After removing that clip, the strands were immersed in saline and divided for various testing:

1 strand → to F. Schiller for SEM, in test tube of sterile water.

5 strands → for microscopic inspection by A. Leibold
↓ then to K. Sullivan for Instron testing.

Fragments from Instroning go to G. Muse for mole. wt. deter., then to D. Barkley for I.R.

PHOTO NONE EXAMINER K. Braun DATE 6-23-87

WITNESS ___ DATE ___

acc# 85-219

ETHICON RESEARCH FOUNDA ON: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 2011 SPECIES canine SEX F BODY WT. 8.0 K gms

DATE 6-24-87 DAYS P.I. 2 yr. KILLED T61 DIED ____ REFERENCES 10 YR. BSE Study

Same as dog # 2009 6-23-87

LC100's were dissected from the fascia. The dorsal LC100 was cut off the sutures and the suture bundle was extracted from the fascia by pulling on the ventral LC100. After removing that clip, the strands were immersed in saline and divided for various testing:

1 strand → to F. Schiller for SEM, in test tube of sterile water
5 strands → microscopic inspection by A. Leibold
then to K. Sullivan for Instron testing.
Fragments from Instroning go to G. Muse for mole. wt. determination
then to D Burkley for IR.

PHOTO _____ EXAMINER K. Braun DATE 6-24-87

WITNESS _____ DATE _____

acc# 85-219

ETHICON RESEARCH FOUNDATION: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 2017 SPECIES canine SEX F BODY WT. 10.1 kgms

DATE 7-8-87 DAYS P.I. 2 yr. KILLED T-61 DIED ___ REFERENCES 10 yr. BSE Study

Same as dog # 2011 (6-24-87)

LC 100's were dissected from the fascia. The dorsal LC100 was cut off the sutures and the suture bundle was extracted from the fascia by pulling on the ventral LC100. After removing that clip, the strands were immersed in saline and divided for various testing.

1 strand → to T. Schiller for SEM, in test tube of sterile water.
5 strands → microscopic inspection by A. Leibold
then to K. Sullivan for Instron testing.

Fragments from Instroning go to J. Muse for mole. wt. determinations
then to D Burkley for I.R.

PHOTO ___ EXAMINER K. Braun DATE 7-8-87

WITNESS ___ DATE ___

acc# 85-219

ETHICON RESEARCH FOUNDA[illegible]N: NECROPSY AND TRIM RECORD

ACCESSION# 85-219 ANIMAL# 1996 SPECIES canine SEX F BODY WT. 22 lbs ~~gms~~

DATE 12-10-86 DAYS P.I. 18 mo. ~~KILLED~~ ~~DIED~~ REFERENCES 10 yr. PROLENE study.

On 12-10-86, dog # 1996 was anesthetized and a round, denuded, ulcerated growth was removed from the skin over implant site #2 (left dorso-lateral thorax).

Histologic evaluation is requested.

PHOTO _____ EXAMINER K. Braun DATE 12-19-86

WITNESS _____ DATE _____

acc# 85-219

12-19-86

85-219 #1996

This tissue consists of a 1.5 cm diameter raised skin mass that is approximately 9 mm in diameter. The mass consists of a fairly discrete aggregation of a fairly homogeneous cell population. The cells have infiltrated the dermal and subcuticular structures so that there is not a discrete border or capsule. The cells have fairly large round to lobulated nuclei with fairly small amounts of eosinophilic cytoplasm. Mitotic figures are present but are not numerous. A toluidine blue stain showed that the vast majority of the cells were negative for metachromatic granules.

Diagnosis: Canine Cutaneous Histiocytoma

Edmund K. LeGrand 4/30/87